# Visual performance and quality of vision questionnaire outcomes in multifocal intraocular lens use

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**TABLE OF CONTENTS**

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**ABSTRACT**

This thesis aimed to investigate the current most advocated methodology for vision-related questionnaire analysis following multifocal intraocular (IOL) implantation. Initial efforts focused on investigating the use and the validity of the Rasch model on a quality of vision (QoV) questionnaire at two postoperative periods. The research then focused on the effect of lifestyle on the QoV questionnaire and the importance of preoperative subcategorisation of groups to allow adequate assessment of QoV.

The QoV questionnaire was then utilised to assess the visual performance and QoV of rotationally asymmetric multifocal IOLs. The individual visual symptom items of the QoV questionnaire and an overall 0-10 score were used to compare QoV between postoperative periods and asymmetric multifocal IOLs. The visual performance and QoV of an asymmetric multifocal IOL was compared at 3 and 12 months. Next the two commercially available asymmetric multifocal IOLs were compared 12 months postoperatively. Additionally, the effect of residual postoperative astigmatism upon the QoV obtained using the asymmetric multifocal IOLs was further investigated.

Rotationally asymmetric multifocal IOLs can be placed in different rotational positions and different powers of near additions (add) are available. To further investigate the effect of different IOL placement on postoperative outcomes a superonasal placement in the dominant eye, with a lower near add power, in combination with inferonasal placement in the nondominant eye was investigated.

Overall, the research reported various shortcomings of the current analysis of vision-related questionnaires and outlined an alternative approach in how to utilise the Rasch model in QoV measurements. The research also defined clear preoperative clinical parameters and intraocular surgical techniques to maximise postoperative visual performance and QoV achieved when implanting asymmetric multifocal IOLs.

**Keywords**

**Quality of vision; patient reported outcomes; subjective questionnaire; asymmetric multifocal IOLs; visual performance**

**ABBREVIATIONS**

| | |
|---|---|
| Add | Addition |
| AL | Axial length |
| AMD | Age-related macular degeneration |
| ANOVA | Analysis of variance |
| CDVA | Corrected distance visual acuity |
| CMO | Cystoid macular oedema |
| CTT | Classical test theory |
| D | Dioptre |
| DCIVA | Distance corrected intermediate visual acuity |
| DCNVA | Distance corrected near visual acuity |
| ECCE | Extracapsular cataract extraction |
| fTBUT | Fluorescein-tear breakup time |
| HOAs | Higher-order aberrations |
| ICCs | Items Characteristics Curves |
| ICCE | Intracapsular cataract extraction |
| IOL | Intraocular lens |
| IOLs | Intraocular lenses |
| IRT | Item response theory |
| JMLE | Joint maximum likelihood estimation |
| LASEK | Laser-assisted subepithelial keratomileusis |
| LASIK | Laser in situ keratomileusis |
| LoA | Bland-Altman limits of agreement |

| | |
|---|---|
| MMLE | Marginal maximum likelihood estimation |
| MNSQ | Mean square |
| OVDs | Ophthalmic viscosurgical devices |
| PCA | Principal component analysis |
| PCI | Partial coherence interferometer |
| PCM | Partial credit model |
| PMMA | Polymethylmethacrylate |
| PROs | Patient reported outcomes |
| QoL | Quality of life |
| QoV | Quality of vision |
| RSM | Rating scale model |
| RLE | Refractive lens exchange |
| SD | Standard deviation |
| SE | Spherical equivalent |
| SMILE | Small incision lenticule extraction |
| UDVA | Uncorrected distance visual acuity |
| UIVA | Uncorrected intermediate visual acuity |
| UNVA | Uncorrected near visual acuity |
| UV-B | Ultraviolet-B |

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**SUMMARY**

The aim of this doctoral research is to investigate the use of ophthalmic questionnaires in assessment of quality of vision (QoV) following asymmetric multifocal intraocular lens (IOL) implantation. Ophthalmic questionnaires are now commonly developed by Rasch analysis and the Rasch model has been utilised to reevaluate and indeed redevelop current existing ophthalmic questionnaires. Asymmetric multifocal IOLs are commonly implanted in cataract surgery and refractive lens exchange (RLE) and the use of subjective questionnaires is now an important postoperative assessment to outline the outcomes of such procedures. Therefore, this thesis also sought to outline QoV outcomes and objective visual outcomes of rotationally asymmetric multifocal IOLs and investigate methods to enhance postoperative outcomes.

The general introduction of this thesis outlines the conception of the IOL, its impact in cataract surgery and how development has progressed since its first implantation. In addition, the methodologies for questionnaire development including Rasch analysis, the current most advocated approach, is outlined.

To date many questionnaires have been developed to measure various subjective traits, such as visual disability, impact of vision on daily activities and overall satisfaction. Nowadays, questionnaires are widely accepted as an important aspect of clinical assessment for various treatments and interventions. Therefore, it is important that questionnaires are developed accurately and measure the trait they are designed to measure, and much research has been dedicated to the development and assessment of ophthalmic questionnaires. One such instrument is the QoV questionnaire that is designed to assess the latent trait of QoV, which is a measure

of a patient's unique perception of their own vision and is described as a subjective entity based on multiple factors, including visual and psychological factors. This questionnaire was developed using Rasch analysis and in Paper I of this thesis the application of Rasch analysis was assessed within the context of the QoV questionnaire at two postoperative time points, to outline the current shortcomings of Rasch analysis in the interpretation of questionnaire data. Additionally, this paper outlines a novel stratified approach of Rasch analysis that is effective as a decision support tool at population and individual level. At population level, the prevalence of symptoms across different cohorts of patients can be determined which allows better characterisation of patient groups preoperatively and an appropriate follow-up postoperatively. At individual level, the new approach enables one to identify patients with poor QoV. Paper II within this thesis attempts to assess the impact of lifestyle on a revised QoV questionnaire. The aim was to outline the use of the new stratified approach for Rasch analysis to highlight the importance of preoperative subcategorisation of patients for adequate assessment of QoV. These papers will help clinicians understand and use questionnaires appropriately.

The aim of cataract surgery is to improve visual acuity and ultimately enhance a patient's functional vision. The modernisation and development of surgical techniques has allowed surgeons to accurately predict and achieve a chosen postoperative refractive outcome and modern multifocal IOLs make complete spectacle independence possible. Multifocal IOLs provide a range of clear vision, however side effects can occur, including blurred vision and dysphotopsias, such as glare, haloes or starbursts. There are various designs of multifocal IOLs with the newest being a rotationally asymmetric multifocal IOL which provides multifocality through separate distance and near zones within the IOL optic. Paper III and IV in this thesis sought to determine the objective outcomes and subjective QoV achieved by new rotationally asymmetric multifocal IOLs and compared the two commercially available asymmetric multifocal IOLs. Additionally, in paper V the impact of residual astigmatism on QoV was determined. This is important to inform clinicians of the postoperative outcomes, including how the performance of the IOL changes over time to subsequently aid clinical decisions and patient management.

Asymmetric multifocal IOLs can be placed in different rotational positions and some research has been dedicated to investigating the impact of differing rotational positions upon postoperative outcomes. Additionally, the near segments of asymmetric multifocal IOLs are available in different dioptric powers. The higher near addition (add) power provides better near vision and the lower near add power provides superior intermediate vision. This provides the surgeon with different options for different lifestyle demands. The placement of near segments in different rotational positions in combination with different near add powers has not yet been fully investigated, therefore this thesis sought to determine the objective outcomes and the subjective QoV outcomes achieved with different rotational positions in combination with a lower near add power. This will help determine if placement of different near adds in varying rotational positions provides improved postoperative outcomes and therefore further enhance the options available to the surgeon.

The work presented in this thesis adds to the current knowledge base surrounding subjective assessment through questionnaires. This research presented shortcomings of the current analysis of vision-related questionnaires and outlined a novel approach of Rasch model for adequate QoV measurements. Additionally, this research will contribute to improvement in postoperative outcomes, including QoV assessment, following asymmetric multifocal IOL implantation by providing a greater understanding of objective and subjective outcomes and outlining methods to enhance postoperative outcomes.

The main aims of the research presented within this thesis are to:

- To investigate the shortcomings of Rasch analysis for the development of a QoV questionnaire, and to present a novel approach for the use of Rasch analysis to enhance subjective questionnaire assessments.
- To assess the impact of lifestyle on a QoV questionnaire and outline the appropriate use of the QoV questionnaire through preoperative subcategorisation of patients.
- To inform clinicians of the objective and subjective postoperative outcomes of rotationally asymmetric multifocal IOLs.
- To optimise postoperative outcomes following asymmetric multifocal IOL implantation by outlining important preoperative clinical considerations.

# 1. GENERAL INTRODUCTION

Richard N. McNeely

## Contributions

Richard N. McNeely carried out all research unless otherwise stated

## 1.1 Cataract

The natural crystalline lens of the eye is a transparent, biconvex, avascular structure enclosed by a capsule, located in front of the vitreous body and behind the iris. The lens is formed from ectoderm tissue and becomes thicker and more compact with age as newly produced epithelial cells elongate to form fibres throughout life, with older cells becoming progressively more deeply located (Kanski, 2007). The lens, along with the cornea, refracts light onto the retina, and, unlike the cornea, is able to alter the focusing power of the eye by changing shape (Asbell et al., 2005). The lens changes shape through contraction of the ciliary muscle and relaxation of the zonule which results in the capsule creating a steeper lens shape (Bennett and Rabbetts, 1998). This is called accommodation and it allows the eye to view objects at a range of distances through changing the focal length of the eye.

The natural lens can lose its transparency and any opacity of the lens is defined as a cataract, and can occur in one or both eyes. There are three main types of cataract depending on the location within the lens and the different types of cataract can occur independently or in combination (Asbell et al., 2005). The three classifications of cataract are nuclear, cortical and posterior subcapsular. The cause of cataract is not yet fully understood; therefore, many studies have investigated the possible risk factors and ways to prevent cataract formation. Cataract occurs with increasing age, with a study in Australia highlighting that the prevalence of cataract increases with every decade after the age of 40. This study found the prevalence of cataract to be 3% and 2.36% for males and females respectively for patients in their 40s. This increased to 7.47% and 6.92% for individuals in their 50s, and the prevalence for those in their 60s was 22% and 30.3%. Males and females in their

70s had a 48.1% and 61.0% prevalence of cataract which further increased to 79.3% and 92.6% in their 80s, and males and females respectively in their 90s had a prevalence of 98.8% and 98.6% (McCarty et al., 1999). Other personal traits such as genetic factors could account for the development of cortical cataract (Hammond et al., 2001) and the severity of nuclear cataract (Hammond et al., 2000). Additionally, cataract has been found to be more prevalent in females, and associated with cigarette smoking, alcohol use and exposure to ultraviolet-B (UV-B) radiation (West et al., 1998; Vrensen, 2009). Another risk factor for the development of cataract is diabetes with a higher incidence and faster progression of cataract found in individuals with diabetes. Harding et al., (1993) outline that diabetes is a significant risk factor for cataract, where they found that 13.9% (101 out of 723 subjects) of cataract patients had cataract caused by diabetes. The subjects were aged between 50-79 years and the risk did not significantly increase with age however females were more at risk. The use of corticosteroids has also been shown to elevate the incidence of posterior subscapular cataract (Asbell et al., 2005).

## 1.2 The effect of cataract

### 1.2.1 The effect of cataract on visual performance

Cataract can have a significant effect on visual function. Patients may report a range of symptoms, such as blurred vision, glare with bright lights, colours appearing dim, haloes around lights and that their glasses are now ineffective. Early cataract may not have any effect on visual function and a patient may not even be aware of the presence of the cataract. However, the symptoms usually increase in severity with time as the cataract matures.

In the clinical setting, visual function is generally assessed through visual acuity testing. The presence of cataract has been found to cause a significant reduction in unaided visual acuity as highlighted in a study by Hong et al., (2013) where it was found that cataract accounted for 48.5% of unilateral or bilateral visual impairment in a population over 49 years old in Australia. Further to visual acuity testing, it has been suggested that to get a true measurement of a patient's visual function, a contrast sensitivity assessment is required (Koch, 1989; Adamsons et al., 1996). Various studies have assessed contrast sensitivity and have found a reduction with the presence of cataract (Elliott and Situ, 1998). Another symptom that has been found to be significantly induced is glare disability (Asbell et al., 2005).

This reduction in objective visual function has been shown to have a significant effect on mobility, everyday activities and physical performance (Salive et al., 1994), and reduced visual function has been associated with reduced quality of life (QoL) (Knudtson et al., 2005). This highlights that cataract can have not only a significant effect on a patient's objective visual function, but also upon their everyday life. Additionally, the impact of visual impairment is emphasised in two further studies where it is suggested that poor visual function can have a similar effect on an individual's life as other medical conditions such as stroke (Chia et al., 2004), and a correlation between visual impairment and increased mortality has been found. McCarty et al., (2001) shows that visual impairment increases risk of death however they state that there is some evidence that death is caused by other factors including accidents.

### 1.2.2 The global effect of cataract

Cataract is the leading cause of blindness in the world and accounts for nearly 48% of worldwide blindness with 90% of those individuals living in developing countries (Resnikoff et al., 2004). Most people with cataract causing blindness are in developing countries because of the lack of adequate access to treatment. A review article by Vrensen, (2009) outlines the occurrence of blindness across different global regions, highlighting that the prevalence of blindness caused by cataract is 5% in Western Europe and Australia/Japan compared to 52.5% in Africa or 49.0% in the Middle East. The significantly lower prevalence of cataract in developed countries is due to the superior and more widely accessible treatments. However, cataract treatment in developed countries comes at a significant cost with the European Union expenditure in excess of 2 billion Euros in 2002 and cataract surgery is the highest expenditure of the US Medicare System (Vrensen, 2009). It is considered that the incidence of cataract will increase with a growing and aging population (Asbell et al., 2005), and is therefore expected to become more of a burden as the prevalence of blindness is likely to increase in developing countries and cause more pressure on surgical provision in developed countries.

## 1.3 Treatment of cataract

Currently the only effective treatment of cataract is the surgical removal of the lens. Surgical removal of cataract is one of the oldest medical procedures with the procedure dating back to 800BC (Roy et al., 1975), and over this period the procedure has developed and improved significantly. The improvement in surgical techniques and equipment has resulted in cataract treatment providing excellent visual outcomes with high patient satisfaction, and is now the most commonly performed medical procedure (Linebarger et al., 1999) with millions of people across the world receiving and benefitting from cataract treatment.

### 1.3.1 Surgical interventions for cataract

The earliest documented method of cataract treatment is “couching” which is one of the oldest surgical procedures (Ascaso and Huerv, 2013). The method of “couching” was utilised to dislocate the cataractous crystalline lens (Ashwin, 2009). The lens was dislocated, with a needle, to fall backward and downward into the vitreous cavity (Asbell et al., 2005). This procedure is now rarely performed and is only used in areas with limited access to skilled surgeons and modern surgical equipment (Asbell et al., 2005). Couching has a very high complication rate and a study in Africa outlined very poor visual outcomes with 42.6% of eyes remaining blind (Gilbert et al., 2010).

The method of “couching” was then replaced by cataract extraction surgery where the cloudy natural lens is removed from the eye. The extraction procedure has the obvious advantage that the lens is no longer in the eye, and therefore there is no risk of the lens migrating back into the visual axis (Ascaso and Huerv, 2013). The first recorded extraction of cataract was performed by Daviel in 1748 (Ridley, 1952). There are two methods of cataract extraction surgery. In the first method, extracapsular cataract extraction (ECCE) surgery, an incision of 10 to 11 mm is made at the corneal-scleral junction and a capsulotomy is made to carefully remove the anterior lens capsule. After making an opening in the anterior lens capsule the lens nucleus is prolapsed and removed through the incision with the posterior lens capsule remaining intact (Linebarger et al., 1999). An alternative method is intracapsular cataract extraction (ICCE) surgery. This procedure involves removal of the entire lens within the capsular bag through a large 180° incision at the junction of the cornea and sclera (Linebarger et al., 1999). ICCE surgery is now rarely utilised, however it may be indicated for complicated cases, such as a partly dislocated lens (Asbell et al., 2005). Following the removal of the clouding natural lens through either ICCE or ECCE the patients require aphakic glasses to restore visual acuity.

It was not until the 1940s that the procedure and equipment could provide effective treatment. Until this point only those with very poor vision could be treated and there were still significant risks, such as infection, for those who received surgery (Metcalfe et al., 2005).

ICCE was the procedure of choice in the first four decades of the 20$^{th}$ century (Linebarger et al., 1999), however ECCE gained popularity following World War II in conjunction with improved surgical equipment. ECCE provides various benefits, such as reducing the risk of retinal detachment and preventing forward bulging of the vitreous humour (Ridley, 1952). However, it was not until the introduction of the intraocular lens (IOL) that major advancement was seen in cataract treatment, which consequently increased the popularity of ECCE because the benefit of maintaining the posterior capsule became apparent.

### 1.4 The conception of the intraocular lens

The IOL was conceived by Harold Ridley and following years of work the first IOL was implanted in 1949 (Ridley, 1952). Ridley's clinical experience made it apparent that the then current treatment of cataract was only half completed following removal of the natural lens (Apple and Sims, 1996). Additionally, following a day of surgery a student mentioned that it would be very beneficial if a clear lens could replace the now extracted natural lens, and this further convinced Ridley that sole removal of the lens was not a complete treatment. Therefore, Ridley embarked on his work developing the IOL. Ridley described that there were three problems to be solved; to decide on a suitable lens material, determine the power and size of the lens and to develop an appropriate insertion method (Ridley, 1952). The introduction of the IOL has led to great advances in cataract treatment, with surgeons now able to provide patients with improved visual acuity, not only through the removal of the clouding lens but correction of the remaining refractive error. This allowed significant improvement in postoperative visual acuity in contrast to leaving a patient aphakic and therefore requiring corrective lenses, which were thick and heavy and often created debilitating distortions and aberrations (Ridley, 1952).

### 1.4.1 The early intraocular lens properties and procedure

Ridley, (1952) outlined that the choice of material for the IOL was between "plastic" methacrylate compounds and glass because both are chemically inert in tissue fluids. Ridley had observed that fragments of polymethylmethacrylate (PMMA), generally known as Perspex, lodged in the eye of pilots from shattered cockpit windows during World War II did not cause a reaction within the eye.

Furthermore, it was well recognised that glass can remain in the eye without any reaction. PMMA was determined to be the most appropriate choice because it was lightweight (Ridley, 1952), and PMMA is still widely utilised as an IOL material, however the most common materials are now acrylic and silicone.

Ridley sought to create a lens that closely matched the natural human lens in refractive index and power, however this was very difficult to achieve. To develop an IOL that was safe and that closely matched the natural human lens required various considerations. The first design had a standard length of 8.35 mm which was 1 mm less than the natural crystalline lens to avoid disruption of the ciliary region. The early IOL was 2.4 mm thick and was produced to have anterior and posterior curvatures similar to the natural crystalline lens. Early procedures resulted in high over correction resulting in alterations in the dioptric power (Apple and Sims, 1996). The lens also contained a peripheral notch to securely hold the lens with forceps during the procedure (Ridley, 1952). The refractive power of the lens in air was +74 dioptre (D) and in the aqueous fluid it was +24 D.

Ridley recommended ECCE to extract the cataractous lens (Ridley, 1952), and outlined that if the entire posterior lens was cleared through ECCE the IOL can be inserted, but if it is not the eye should be closed and IOL implantation should be performed later.

### 1.4.2 Early Intraocular outcomes

Ridley outlined the outcomes of 27 eyes following monocular IOL implantation (Ridley, 1952). The first two IOL implantations were significantly overcorrected because the lens was too thick and the magnitude of refractive power was too great.

In this early study, Ridley outlines that the remaining 25 eyes displayed an improvement postoperatively. The study also concluded that an IOL can be implanted into the eye following cataract removal and subsequently free the patient from the use of thick aphakic glasses postoperatively. However, Ridley stated that overconfidence was unjustified and further work is required.

The induction of any new scientific treatment or technique will present difficulties and undoubtedly a period of development is required. This was the case with the IOL and 10 years from its introduction Ridley, (1960) described that the IOL had clear advantages over leaving a patient aphakic and many patients still had satisfactory results 10 years later. However, because of the technical difficulties and complications, such as iridocyclitis and lens instability, Ridley, (1960) noted that most surgeons moved to anterior chamber implantation introduced by Strampelli in 1954. The advantage of anterior chamber IOLs were that it was a less severe operation, there was no requirement of support from the posterior lens capsule, the optical requirements were more easily calculated and it was easier to explant the IOL (Ridley, 1960).

The complications associated with posterior chamber IOLs and a lack of understanding of the corneal endothelium physiology in anterior chamber IOLs resulted in the near abandonment of IOL implantation in the late 1960s to the early 1970s (Olson et al., 2003).

## 1.5 Further advances in cataract surgery

In the coming years, there were significant advancements in cataract extraction surgery with IOL implantation. In 1963 Charles Kelman turned his attention to the possibility of reducing the corneal incision size. This was achieved by phacoemulsification which utilises ultrasound to fragment the cataract and subsequently allow the fragmented cataract to be removed through a corneal incision of approximately 2-3 mm. The first devices were made commercially available in 1970 (Metcalfe et al., 2005). The advantage of phacoemulsification was that it allowed good anterior chamber control, and therefore maintained intraocular pressure, resulting in less likelihood of vitreous prolapse. Also, phacoemulsification allowed faster visual recover with less induced astigmatism, and, if a patient required further treatment, it is less likely that the smaller incision will reopen (Linebarger et al., 1999). However, the benefits of a smaller incision size would not be worthwhile if the incision had to be increased to allow the implantation of an IOL. Therefore, a foldable IOL was pioneered by Thomas Mazzocco (Olson et al., 2003) and implanted into the posterior chamber in the early 1980s in combination with phacoemulsification. Additionally, viscoelastic substances, more recently called ophthalmic viscosurgical devices (OVDs) were introduced to be used with phacoemulsification in the mid 1970s by Andre Balaz. The use of these substances during cataract surgery enables protection of the corneal endothelium from mechanical damage (Olson et al., 2003), and maintains intraocular spaces (Linebarger et al., 1999). The most commonly used substance is sodium hyaluronate. Prior to viscoelastic substances balanced salt solution and air were used but both substances were quickly lost from the anterior chamber during the procedure (Bollinger, K and Smith, S.D, 2014).

These improvements in surgical technique during the second half of the 20$^{th}$ century vastly advanced cataract treatment. The procedure became more controlled, safer and quicker with a much faster visual recovery. Additionally, it allowed a short recovery period compared to the previous surgeries that required a week or more hospitalization. Phacoemulsification is now considered the standard method with 97% of surgeons reporting to use this methodology (Leaming, 1998), in combination with foldable IOLs, and viscoelastic techniques.

As discussed, the early IOL material utilised was PMMA and this is the material that was used for Ridley's maiden IOL implantation in 1949. However, the material used for IOLs has developed and changed over time. Nowadays, the most common IOL material utilised is hydrophobic acrylic, which has an excellent inflammatory profile and uveal biocompatibility (Olson et al., 2003).

## 1.6 Biometry

The calculation of IOL power is an important aspect of modern cataract extraction surgery. The correct selection of IOL power enables the surgeon to accurately target a postoperative refractive outcome, which has become increasingly important with a rise in patient expectations. Similar to the surgical techniques and IOL design preoperative assessment and biometry has improved since the first IOL implantation. To achieve optimum postoperative outcomes accurate biometry measurements along with application of the correct lens power formula is essential. Biometry includes the measurement of the anatomical characteristics required to accurately calculate the IOL power. This includes measurement of the axial length, keratometry and anterior chamber depth. The methods utilised to make such measurements have also developed and changed since the first IOL implantation. The use of ultrasound has been the standard method for biometry for decades measuring axial length and anterior chamber depth. Sahin and Hamrah, (2012) outline the use of ultrasound in biometry. This method generates a high frequency sound-wave through oscillations of a special crystal embedded in a probe. The resultant echoes are displayed on the oscilloscope screen providing the required measurements through assessment of the heights and distances of the echoes. Ultrasound biometry requires contact with the eye either by a transducer or a saline immersion bath. There are disadvantages with this method due to contact with the cornea where corneal indentation and off-axis measurements can occur, and there is also the risk of infections (Sahin and Hamrah, 2012).

Optical coherence tomography has since been introduced as a non-contact method for biometry measurements. Optical coherence tomography utilises ultrasonic pulse-echo imaging without corneal contact through measuring echo delay and intensity of infrared light instead of acoustic waves reflected back from the different tissue interfaces (Drexler et al., 1998). This method has been found to be useful in biometry and tomography in ophthalmology. Further developments have seen the introduction of the partial coherence interferometer (PCI) which is a dual beam version of optical coherence tomography. This dual beam version eliminates the influence of longitudinal eye movements and can measure arbitrary intraocular distances as well as angles parallel to the visual axis, and can produce cross-sectional retinal images (Findl et al., 2001).

It is well known that accurate preoperative measurements are essential for IOL power calculation. However, another important aspect is the IOL power calculation formula, and there is some debate regarding which is the best formula to use. The original method of IOL power calculation was to use the preoperative refractive error which often resulted in a significant residual refractive error. The method to predict IOL has since developed with biometry measurements soon incorporated into IOL power estimation. The first generation of IOL power calculation formulas used the axial length, the power of the cornea, and the constant of the IOL design to estimate the required IOL power. A large number of cases were studied and linear regression analysis performed to determine a formula for predicting IOL power (Park, 2014). This provided the first regression formula known as the SRK formula. However, it was found that this formula was not accurate with short or long eyes (Dang and Raj, 1989) which led to adjustments in the formula. The SRK II formula was therefore introduced where the constants were altered depending on axial length. The next generation of formulas increased the accuracy further by estimating the position of the IOL based on axial length and keratometry. The formula would calculate the distance from the cornea to the iris plane. This factor is specific to each IOL and can be adjusted according to the surgeon's results (Park, 2014). Another formula was formed using the same method (Hoffer, 1993), and then Retzlaff et al., (1990) followed by developing the SRK/T formula which takes into consideration the position of the IOL and the retinal thickness. A fourth-generation formula has since been introduced which utilises 3 lens constants because the lens geometry is the not the same for all IOL powers (Park, 2014). Furthermore, the anterior chamber depth and in some cases the white-to-white, the refraction, lens thickness and age are also used to further improve predictability, and is often used in unusual eyes. This formula is called the Holladay 2 (Park, 2014).

For each IOL design the manufacturers provide a constant for IOL power calculations because the effective IOL power may alter in the eye due to lens position, lens geometry and lens refractive index. However, the constant varies among IOL designs and surgeons and it is important that each surgeon hones this constant for their own preoperative measurements and surgical technique. These developments have played their part in the advancement of cataract surgery and have provided surgeons with the ability to accurately target a chosen postoperative refractive outcome.

**1.7 Modern day IOLs outcomes**

Cataract treatment developed significantly in the latter half of the 20$^{th}$ century and IOL implantation is now the standard procedure following cataract extraction surgery. The development of the IOL in conjunction with improved surgical equipment and techniques provides a method with excellent and predictable outcomes following cataract surgery. This allows precise surgery with significant vision enhancement which has led cataract extraction surgery with IOL implantation to be the most commonly performed operation in the world (Linebarger et al., 1999). Many studies outline the excellent visual outcomes of modern IOLs where excellent levels of unaided visual acuity are achieved (Calladine et al., 2015; Maxwell et al., 2008; Shah et al., 2015). Additionally, the predictability of modern cataract surgery is very accurate, outlined by a large population study (Aristodemou et al., 2011) which reported 40%, 70% and 95% of eyes were within ± 0.25 D, ± 0.50 D and ± 1.00 D of the target refraction, respectively. Along with good predictability the refractive outcomes of cataract treatment are very stable and the procedure is now very safe with the occurrence of sight threatening complications being rare (Day et al., 2016).

The main objective of cataract extraction surgery is to improve visual acuity and thereby enhance visual function. The improvement in visual function following the removal of cataract should therefore increase the QoL a patient experiences. A study (Desai P et al., 1996) found a significant improvement in QoL at 4 and 12 months postoperatively compared to before cataract extraction surgery with IOL implantation. The patients in this study reported improvement in vision dependent activities and in health related QoL scores, such as mobility and social interaction. A more recent review article (Lamoureux et al., 2011) outlines that the improvement in postoperative visual acuity following cataract surgery relates to a significant improvement in everyday tasks.

It is evident that cataract treatment with IOL implantation has developed into a safe and predictable surgery and restores visual function and ultimately improves QoL. Millions of patients across the world have received IOL implantation providing vast improvements in visual function, allowing patients to return to work and reduce the care that would otherwise be required due to poor sight.

**1.8 The introduction of multifocal intraocular lenses**

Multifocal IOLs were introduced to provide a range of clear vision and subsequent spectacle independence. Multifocal IOLs utilise the concept of simultaneous vision (Davison and Simpson, 2006) to provide multifocality. The multifocal IOL provides 2 or more optical foci which usually means that the multifocal IOL will have at least two dioptric powers. This produces two simultaneous retinal images, resulting in a clear distance image on the retina with a simultaneous blurred near vision image, and when viewing a near object a clear near image with a blurred distance image will be projected onto the retina as shown in figure 1.

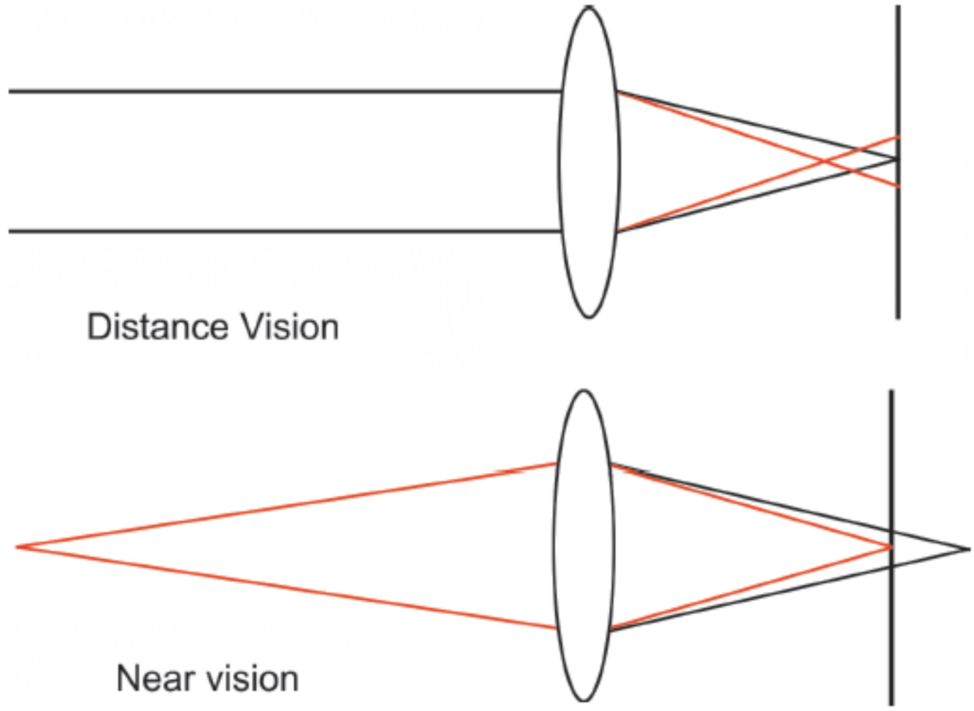


**Figure 1** Simultaneous vision ray diagrams when viewing distance and near images. (Bellucci, 2005)

The first multifocal IOLs were introduced in the late 1980s (de Vries and Nuijts, 2013). Various optical principles have been utilised to provide multifocality, such as of diffraction, refraction or a combination of diffraction and refraction as described in figure 2.

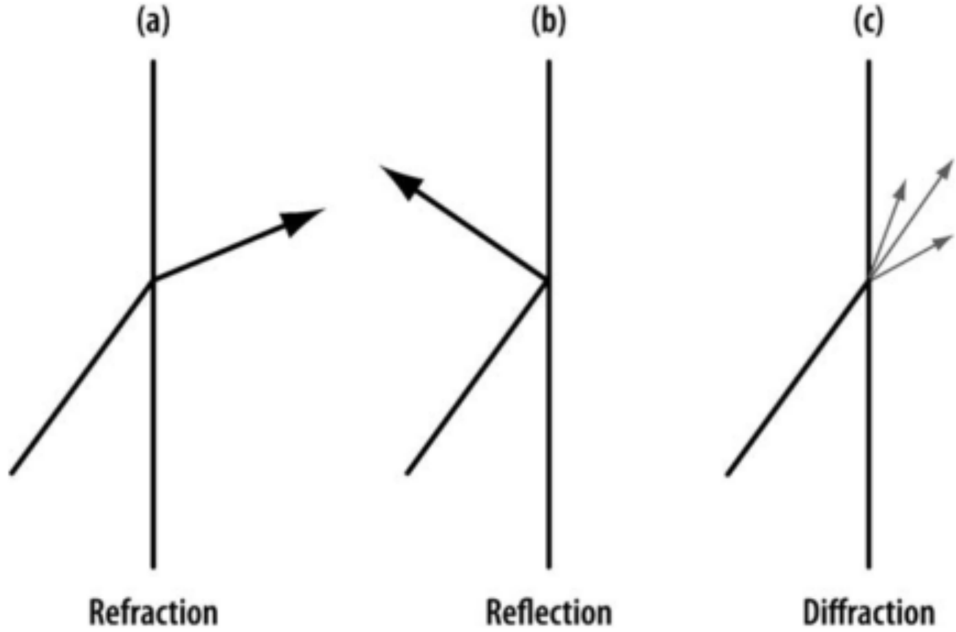


**Figure 2** There are 3 methods to redirect light in a controlled manner: (a) Refraction: The refractive index difference between the 2 materials determines the angle. (b) Reflection: The reflected angle equals the incidence angle. (c) Diffraction: The grating period determines the diffracted angles, and the grating phase structure determines how much light goes into each diffraction order. (Davison and Simpson, 2006)

### 1.8.1 Diffractive intraocular lenses

The diffractive multifocal IOL provides multifocality by diffraction where light is dispersed in numerous directions when it encounters the edge of an obstruction. This occurs because when light hits the edge of an obstruction it is slowed down resulting in a change of direction and therefore causes the light to divide and create two more focal points (de Vries and Nuijts, 2013). The diffractive IOL optic contains different diffractive zones (Figure 3).

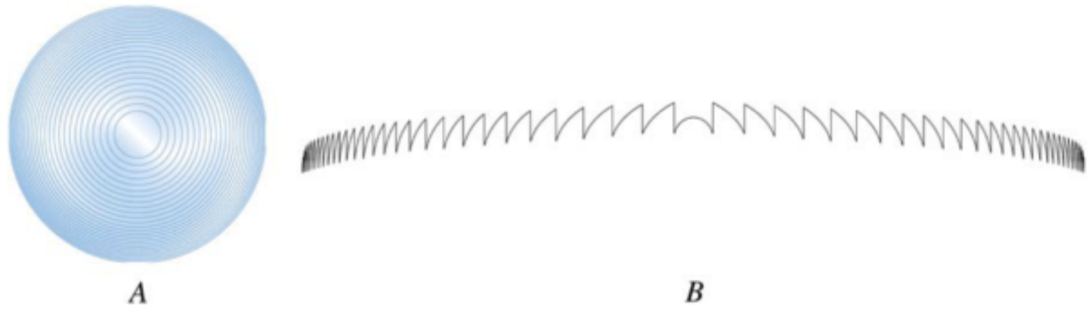


**Figure 3** A diffractive multifocal IOL outlining the different diffractive zones across the optic. (a) Plan view (b) magnified surface profile. (Davison and Simpson, 2006)

These different zones provide phase delays splitting the light into multiple beams which then focus on a predetermined point to provide near focus in combination with the overall curvature of the optic providing the distance focus. Additionally, the step heights are all equal size and the zones between the steps are not refractive because they do not refract light (Davison and Simpson, 2006). With the diffractive IOL design only approximately 41% of the light is directed to distance and 41% to near. The remaining 18% of light is unfocusable because it is lost to higher order diffraction, which results in this light being wasted and will therefore reduce the performance of the IOL (Steinert et al., 1999). The diffractive multifocal IOLs' optical properties remain constant despite changes in pupil diameter and is therefore independent of pupil size (Davison and Simpson, 2006).

Studies have shown that diffractive multifocal IOLs provide visual rehabilitation for both distance and near vision (Sood et al., 2010; Packer et al., 2011). Additionally, Cillino et al., (2008) outlined the satisfaction rates of a diffractive multifocal IOL, finding that patients reported low levels of unwanted dysphotopsias and high spectacle independence.

One finding with diffractive multifocal IOLs is the reduction in postoperative contrast sensitivity, which is an issue when driving because it is commonly performed in low contrast conditions. This led to the introduction of a diffractive multifocal IOL that was distant dominant to enhance distance vision and therefore improve contrast sensitivity for distance, which may be beneficial for driving. However, the distance dominant design caused an inevitable reduction in near vision. Another study outlined the results of combining a distant dominant multifocal IOL in one eye with a near dominant multifocal IOL in the fellow eye (Jacobi et al., 1999). The distant dominant multifocal IOL focuses 70% of light to the distance and 30% of light to near images with the near dominant IOL focusing 70% of light to near and the remaining 30% to distance (Jacobi et al., 1999). This study reported good binocular visual function with 80% of patients achieving spectacle independence postoperatively. An improvement in contrast sensitivity compared to distant dominant multifocal IOLs was observed.

### 1.8.2 Refractive multifocal intraocular lenses

Fully refractive multifocal IOLs consist of concentric rings of varying dioptric power and subsequently direct light to different focal points. Refractive multifocal IOLs are also referred to as multizonal refractive IOLs. Multizone refractive IOLs consist of two different powers in the IOL optic and various models of the IOL have utilised different numbers of zones to provide the multifocality (Figure 4).

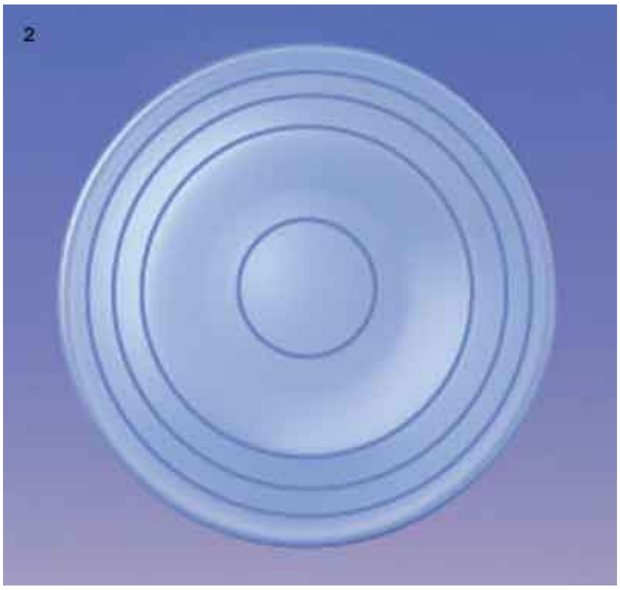


**Figure 4** Image of the refractive multifocal IOL design. The IOL utilises zones of different powers to refract light to distance and near objects to achieve multifocality. (available at: https://www.aao.org/eyenet/article/eyes-on-europe-new-options-in-multifocal-iols [accessed June 2017])

An example of a refractive multifocal IOL is the Array IOL (AMO) which contains 5 zones. The array IOL refracts 50% of light to the distance, 13% to intermediate distances and the remaining 37% to near (Steinert et al., 1999). The Array IOL focuses 100% of light compared to diffractive multifocal IOLs where some of the light is lost to higher order diffraction. However, fully refractive multifocal IOLs are dependent on pupil size because the change in pupil diameter between mesopic and photopic conditions results in exposure of a varying number of concentric rings providing either distance or near dominant viewing. Sen et al., (2004) reported that the AMO Array refractive multifocal IOL provided excellent visual outcomes and patient satisfaction, however there was a reduction in contrast sensitivity and an increase in halo perception, however this seemed to be an acceptable compromise. Javitt and Steinert, (2000) outlined that refractive multifocal IOL patients reported more glare and haloes than a monofocal comparison group, however the multifocal group reported higher overall satisfaction.

### 1.8.3 Apodized diffractive intraocular lens

One principle that has been used to overcome the potential side effects of multifocal IOLs is utilising the natural contraction and dilation of the pupil in different lighting conditions. This results in different amounts of light entering the eye depending on the pupil diameter (Hayashi, 2001). This optical principle is called apodization. Apodized multifocal IOLs consist of taller steps in the centre which reduce in size in the periphery. The IOL is designed in this manner because of the variation in pupil diameter between mesopic and photopic conditions. The pupil dilates in mesopic conditions resulting in more of the steps within the pupil dimeter, and therefore optimising distance viewing. This is beneficial because when an individual is in mesopic conditions, such as driving at night, distance vision is a priority and near vision is not. Additionally, apodized diffractive multifocal IOLs produce less glare and haloes because the distracting out of focus light rays, that can cause such dysphotopsias, are reduced when viewing distant objects through a dilated pupil. Photopic conditions cause the pupil to constrict resulting in a reduced pupil diameter and less diffractive steps within the pupil area. This results in the apodized diffractive multifocal IOL diffracting light equally between distance and near vision. The ReSTOR IOL is an apodized diffractive multifocal IOL and uses a diffractive-refractive design to enhance energy control distribution (Figure 5).

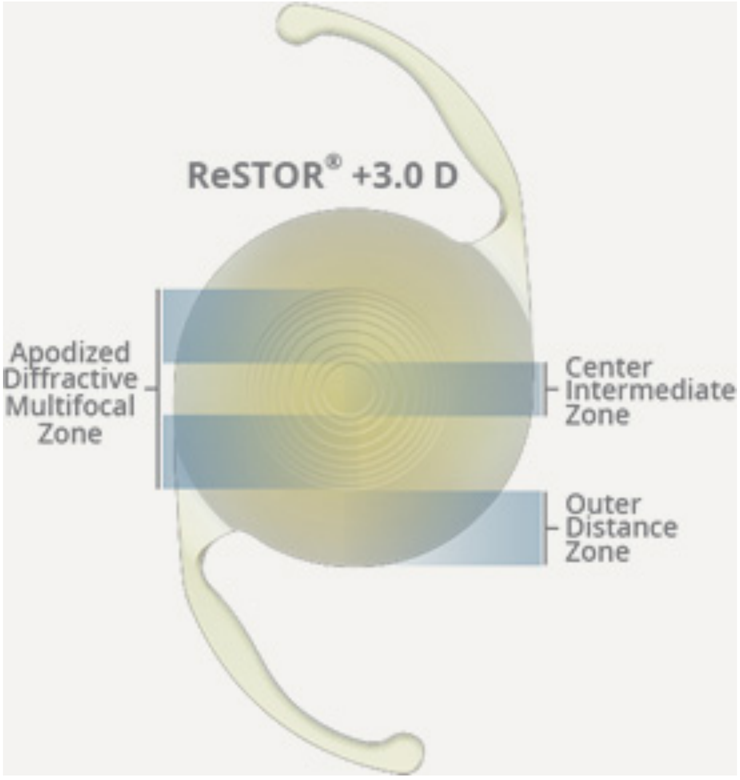


**Figure 5** Image of the ReSTOR IOL.
(available at: https://www.myalcon.com/products/surgical/acrysof-iq-restor-multifocal-iol/restor-30.shtml [accessed June 2017])

The diffractive aspect of the ReSTOR is found within the central 3.6 mm where there are 12 diffractive steps and the refractive aspect is around the periphery of the lens to enhance distance vision (Davison and Simpson, 2006). The ReSTOR IOL is apodized as the step sizes reduce from the centre to the periphery of the IOL optic resulting in more light focused in the distance. At the periphery of the IOL optic there is no diffractive structure and therefore all light focuses in the distance. Additionally, the periphery of the IOL containing a refractive design results in no light being lost to higher order diffractive orders. Studies have found that the optics of the ReSTOR IOL provide better vision properties and reduce unwanted optical phenomena (Davison and Simpson, 2006). A study by Kohnen et al., (2006) outlined the results of the ReSTOR IOL and highlighted good unaided vision with 80% of patients achieving spectacle independence, however some photic phenomena remained. Another study by Alfonso et al., (2007) extensively studied two models of apodized diffractive multifocal IOL. The two different groups both received a apodized multifocal IOL and consisted of 325 and 335 patients respectively. In both groups only 2% were reported to need glasses for near vision, and 4% required glasses when performing either near or intermediate tasks. Additionally, all patients reported visual disturbances between none and moderate and no patient reported having severe glare or haloes. Chiam et al., (2006) reported that 21.3% of patients with ReSTOR IOLs reported to be moderately affected by glare. Furthermore, 3.8% had severe haloes, while 16.3% had moderate haloes. Chiam et al., (2006) found that the visual improvements outweighed the reports of photic phenomena.

### 1.8.4 Trifocal intraocular lenses

Diffractive and refractive multifocal IOLs provide two focal lengths, one for distance and one for near vision. Intermediate vision is poor with these IOLs because the intermediate focal length lies between the two primary foci. Therefore, to enhance postoperative intermediate visual acuity a trifocal IOL has been introduced. The trifocal IOL is 100% diffractive in design and aims to provide intermediate vision without reducing either distance or near visual acuity. Gatinel et al., (2011) extensively outlined the development of the first diffractive trifocal IOL (Finevision). The concept was to combine two diffractive bifocal profiles resulting in a single diffractive profile. The IOL combines the two diffractive zones, one that provides +3.50 D addition (add) and the other +1.75 D add for intermediate vision. The step size of the diffractive zones is apodized because the step height decreases from the centre to the periphery. The IOL focuses more light to the distance at all pupil diameters with the amount of light at distance also increasing with increasing pupil size. Gatinel et al., (2011) also outlined that this design of IOL reduces the amount of light energy lost. This is achieved through integration of the two diffractive optics which allows some of the lost light energy of the second diffractive profile to be used for near vision in the first diffractive profile. This integration of the two diffractive profiles reduces the light energy lost to approximately 15% (Gatinel et al., 2011).

A study outlines the result of the Finevision trifocal IOL and highlighted that this IOL is an effective method of providing distance, intermediate and near visual acuity (Sheppard et al., 2013). While no patient reported any unwanted photic phenomena, this study only included 15 patients. Another available trifocal IOL is the AT Lisa tri 839MP (Carl Zeiss Meditec AG) which has add powers of +3.33 D and +1.66 D. An initial study highlighted that this IOL provided good distance, intermediate and near vision with all patients reporting a high level of satisfaction (Mojzis et al., 2014). Another study showed that the AT Lisa tri 839MP IOL had a high patient satisfaction with 92% saying they would select the IOL again and recommend it despite the presence of some optical phenomena (Kohnen et al., 2016). Furthermore, a study by Marques and Ferreira, (2015) compared these two trifocal IOLs and outlined that both IOLs provided 100% spectacle independence and with low visual side effects. One patient reported experiencing considerable trouble with haloes and glare and no patients reported overwhelming trouble in either group.

### 1.8.5 Aspheric multifocal intraocular lenses

A further development in multifocal IOLs is the introduction of the aspheric multifocal IOL. The aim of aspheric multifocal IOLs is to compensate for the increased spherical aberration of the cornea and therefore decrease the higher-order aberrations (HOAs) of the total optical system (de Vries and Nuijts, 2013). The use of an aspheric multifocal IOL aims to improve image quality, increase range of vision and reduce unwanted side effects such as glare and haloes (Montés-Micó et al., 2009). Aspheric multifocal IOLs have been found to provide superior outcomes to spherical multifocal IOLs (Alfonso et al., 2009), however another study has found that the outcomes between spherical and aspheric multifocal IOLs are comparable (de Vries et al., 2010). One study compared the outcomes of a multifocal IOL with asphericity to the same multifocal IOL but without asphericity. The distance and near visual acuity, and contrast sensitivity were equal between the two designs however the aspheric model displayed significantly better intermediate vision (Alfonso et al., 2008).

### 1.8.6 Mix and match technique of multifocal IOL implantation

The method of implanting a refractive multifocal IOL in one eye and a diffractive multifocal IOL in the fellow eye to improve visual performance and patient satisfaction has also been investigated. This is called mix and match implantation. Favorable long-term visual and spectacle independence was reported in a study that outlines the results of mixing and matching refractive and diffractive multifocal IOLs (Gunenc and Celik, 2008). Another study (Goes, 2007) outlines that the purpose of combining the two optical principles is to provide a range of clear vision without significant visual trade-offs and reports that the visual outcomes of mixing and matching with the Tecnis ZM900 (Advanced Medical Optics [AMO], Santa Ana, Calif) and the AcrySof ReSTOR (Alcon Laboratories Inc, Ft Worth, Tex) were good at a range of distances 2 months postoperatively. However, it should be noted that a limitation of this study is the short follow up time. The report also emphasised that patients should be highly motivated for spectacle independence and be made aware of the of period of neuroadaptation.

### 1.9 Rotationally asymmetric multifocal intraocular lenses

Multifocal IOLs have continued to be developed in order to provide optimal objective visual and refractive outcomes and subjective outcomes following IOL implantation. As outlined most multifocal IOLs are either refractive or diffractive in design. A drawback with multifocal IOL implantation is that some unwanted side effects can occur. Such drawbacks of multifocal IOLs include decreased contrast sensitivity and the presence of dysphotopsias which can result in lower postoperative patient satisfaction (Woodward et al., 2009; de Vries et al., 2011).

In an attempt to further improve the visual and subjective outcomes following multifocal IOL implantation the rotationally asymmetric multifocal IOL has been introduced. The rotationally asymmetric multifocal IOL has been utilised in clinical practice for the last 8 years. This IOL differs from the previous multifocal IOLs because it does not contain concentric rings. The rotationally asymmetric multifocal IOL has a refractive design and splits light into two focal planes through two different sections within the IOL optic, and is therefore rotationally asymmetric. The IOL optic contains a larger distance zone, behaving like a monofocal IOL, with a sectorial-embedded near segment providing the near vision. There are two commercially available rotationally asymmetric multifocal IOLs currently available as shown in figure 6 & 7; the Lentis Mplus IOL (Oculentis GmbH) and the SBL-3 IOL (Lenstec, Inc.).

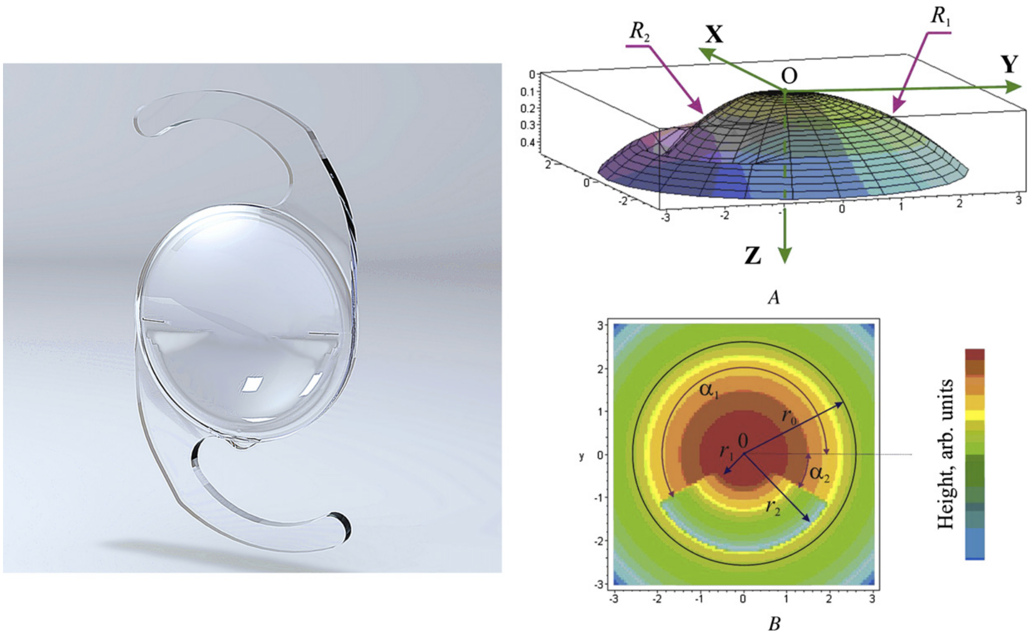


**Figure 6** The Mplus multifocal IOL with a surface embedded near section. (McAlinden and Moore, 2011a)

**Figure 7** The SBL-3 multifocal IOL. (Venter et al., 2014)

The Lentis Mplus IOL was the first multifocal IOL designed in this manner. The SBL-3 has since been introduced and is currently undergoing clinical trial in the United States.

The Lentis Mplus IOL has a refractive design and contains an aspheric distance vision zone embedded with a rotationally asymmetric near zone. The power of the near zone is available in +1.50 D, +2.00 D and +3.00 D. The distance and near principal foci of the IOL are on the optical axis and light hitting the transition area of the near segment is reflected away from the optical axis to prevent diffraction or superposition of interference (Alió et al., 2011). The IOL is a biconvex, acrylic with a hydrophobic surface, single piece multifocal IOL and has an optic length of 6.0 mm and an overall length of 12.0 mm. The Lenstec SBL-3 IOL is a bi-aspheric asymmetric multifocal IOL and contains a larger distance zone combined with a near vision segment in the anterior optic that is available in +2.00 D and +3.00 D add powers. The distance and near zones are separated by a small wedge-shaped transition zone. The near segment occupies 42% of the IOL optic and the IOL optic has a length of 5.75 mm and the IOL has an overall length of 11 mm. The IOL is made from a hydrophobic acrylic material and has a neutral aberration profile (Venter et al., 2014).

The aim of modern day cataract extraction surgery with multifocal IOL implantation is to provide a range of clear vision with the aim of providing spectacle independence. Several studies outline the visual and subjective performance of the first commercially available asymmetric multifocal IOL, the Lentis Mplus IOL. A study by Alió et al., (2011) outlines the clinical outcomes of the Mplus IOL with different near segment add powers. One group had the +1.50 D add and the second group had the +3.00 D add. The study highlighted that both the +1.50 D and the

+3.00 D provided distance and intermediate visual rehabilitation with the +3.00 D providing superior near visual acuity compared to the +1.50 D IOL. To my knowledge there is no study that outlines the clinical outcomes of the +2.00 D add of the Mplus IOL.

An initial study regarding the second rotationally asymmetric multifocal IOL was performed by Venter et al., (2014). This study reported the outcomes of the SBL-3 IOL up to 3 months postoperatively highlighting that bilateral implantation provided excellent unaided visual acuity with a high patient satisfaction. To my knowledge this is the only published paper on the SBL-3 IOL and studies to determine the clinical outcomes at longer postoperative follow-up assessments are required.

One advantage of the new design of rotational asymmetry is that this IOL design improves subjective satisfaction through reduction in photic phenomena and dsyphotopsias, such as glare and haloes. This new design of multifocal IOL contains only one transition zone, between the distance and near segment, resulting in less light scatter and therefore reducing the incidence of photic phenomena and dysphotopsias. Various studies have outlined the subjective outcomes of the Mplus IOL. A study by Muñoz et al., (2011) outlined that 6 months following bilateral Mplus IOL implantation 4 out of 32 patients (12.5%) reported to experience moderate glare and 2 out of 32 patients (6.2%) reported to experience moderate haloes. Additionally, patients were also asked to rate their overall satisfaction on a scale for 0 to 10 with 0 being least satisfied and 10 being the most satisfied, with and mean score of 8.09 ± 1.30 6 months postoperatively. Muñoz et al., (2011) outlined that 27 out of 32 patients (84.4%) were completely spectacle independent.

The Venter et al., (2014) study outlined the subjective outcomes at 3 months following bilateral SBL-3 implantation and highlighted that 75.5% were very satisfied and 18.9% were satisfied with the outcome of the procedure.

### 1.9.1 Rotationally asymmetric versus symmetric multifocal intraocular lenses

As outlined, symmetric multifocal IOLs have been found to provide good distance, intermediate and near vision, however there are some drawbacks affecting overall patient satisfaction (Woodward et al., 2009; de Vries et al., 2011). The new rotationally asymmetric design with the separate distance and near zones in theory should present less optical side effects. There should be less optical side effects because the near zone reflects unwanted side images away from the retina and there are no concentric rings causing either refraction or diffraction in the IOL optic (van der Linden et al., 2012). Several studies have therefore compared the performance of asymmetric multifocal IOLs against the symmetric multifocal IOL design. Alió et al., (2012a) outlined that both the Mplus IOL and an apodized diffractive multifocal IOL (ReSTOR SN6AD3, Alcon Laboratories Inc) equally restored distance visual acuity 3 months postoperatively. The diffractive IOL provided superior best-corrected and uncorrected near visual acuity, however the authors also outlined that this IOL has a +4.00 D add and therefore it is not surprising that it provides better near visual acuity. The zonal refractive IOL provided better intermediate vision and contrast sensitivity. Alió et al., (2012b) compared the Mplus IOL to a fully diffractive rotationally symmetric multifocal IOL (Acri.Lisa 366D, Zeiss, Oberkochen, Germany). This study displayed that the asymmetric multifocal IOL provided better intermediate vision and contrast sensitivity, however the symmetric multifocal IOL provided better distance and near vision. In another study, van der Linden et al., (2012) compared the Mplus IOL to a diffractive apodized multifocal IOL (Restor SN6AD1). There was no significant difference in distance visual acuity and both groups reported spectacle independence in good lighting. There was no significant difference between the two groups in the presence of haloes. The study found that 83.33% of Mplus patients and 98.6% of symmetric multifocal IOL patients were satisfied with their postoperative vision. However, this study was not randomised which may have induced selection bias.

To my knowledge there is no study that compares the SBL-3 IOL to rotationally symmetric multifocal IOLs.

### 1.9.2 Important Preoperative considerations

As outlined the asymmetric multifocal IOLs have different powers available for the near segment and because of the asymmetric design of the IOL the near add can be placed in different rotational positions. Therefore, there are various preoperative factors that need to be consider when implanting asymmetric multifocal IOLs.

A study by Alió et al., (2011) compared the visual and refractive outcomes of the Mplus IOL with a +1.50 D add and +3.00 D add. They found that the +3.00 D add provided significantly better uncorrected near visual acuity (UNVA) and distance corrected near visual acuity (DCNVA) at 6 months. The study concluded that both models restored distance and intermediate visual acuity however full near visual rehabilitation was achieved with the +3.00 D design. A further study by McAlinden and Moore, (2011a) implanted a +3.00 D add Mplus IOL in the nondominant eye and a +1.50 D add in the dominant and assessed the visual and refractive outcomes and the postoperative QoL. This study found good unaided visual acuity at 3 months with good contrast sensitivity and an improvement in QoL responses.

The asymmetric design of the multifocal IOL allows the vertical axis of the multifocal IOL to be placed in different rotational positions. The manufacturers' guidelines are to place the near segment inferiorly with slight nasal deviation, however they do state that the near segment can be positioned in other rotational locations without side effects. A study by de Wit et al., (2015) compared bilateral superotemporal placement versus bilateral inferonasal placement of near segments following anecdotal observation of superiorly placed or rotated IOLs reporting fewer dysphotopsias. This study found that there was no significant difference in objective and subjective outcomes between the superotemporal and inferonasal placed near segment groups. Another study found that either inferiorly, superiorly or temporally placed near segments produced no significant difference in visual performance 1-month following Mplus IOL implantation (Song et al., 2016).

The near add power selected and the near segment position are important preoperative considerations in rotationally asymmetric multifocal IOLs and this concept has not yet been fully investigated.

A review by Moore et al., (2016) highlights the important preoperative considerations required for optimum postoperative objective and subjective outcomes. Moore et al., (2016) outline that pupil diameter and consideration of pupil shift is an important preoperative consideration when implanting asymmetric multifocal IOLs. Pupil shift is the slight change in the pupil centre between mesopic, photopic and pharmacologically dilated conditions (Pazo et al., 2016). This can be assessed preoperatively allowing for analysis between the mesopic and photopic pupil resulting in IOL placement in the physiological centre of the constricted pupil. With asymmetric multifocal IOLs it is important to have adequate areas of the distance and the near zones within the pupil centre. Pazo et al., (2016) outline a case where a patient complained of blurred vision when in bright light conditions. It was noticed that when the pupil was constricted the pupil area consisted of mostly the near segment. The IOL was therefore rotated in the dominant eye from inferonasal placement to a superotemporal position resulting in a significant improvement in visual acuity and satisfaction. To ensure adequate distance and near zone areas within the pupil centre Moore et al., (2016) highlight that selecting patients with a preoperative photopic pupil size greater than 3 mm helps to achieve adequate exposure of the distance and near segments. Selection of an adequate preoperative pupil diameter is also important to maintain good visual results and patient satisfaction in the future. It is well known that pupil diameter decreases with age and to ensure postoperative outcomes are maintained an adequate preoperative pupil dimeter must be selected to guard against decreasing pupil size and therefore loss of exposure of either the distance or near zones of the IOL optic.

Proper postoperative patient selection and counselling is essential prior to implantation of a multifocal IOL, however the various factors such as near add power and placement have not yet been fully investigated. Further studies into asymmetric multifocal IOLs should help determine the optimum placement of the near segment to further improve postoperative outcomes and therefore patient satisfaction.

### 1.10 Other intraocular lens designs and methods for spectacle independence

There are other methods currently used to provide patients with spectacle independence following cataract extraction surgery. These include other IOL designs and different combinations of monofocal IOLs to provide a range of clear vision.

### 1.10.1 Extended depth of focus intraocular lenses

As outlined, multifocal IOLs can produce unwanted side effects, such as dysphotopsias. In an attempt to reduce the prevalence of such unwanted side effects extended depth of focus IOLs have been introduced. One such extended depth of focus IOL is the Tecnis Symfony IOL (Abbott Medical Optics, Inc.). This IOL is based on diffractive achromatic technology. The IOL utilises a novel diffractive optic design to extend the range of vision. Additionally, the IOL corrects chromatic and spherical aberration to improve image quality, improve contrast sensitivity and reduce dysphotopsias. It has been found that ocular chromatic aberrations affect the optical quality of an image because it causes blur and reduces contrast sensitivity (Negishi et al., 2001). Therefore, the correction of this aberration results in sharper focus of light, and improves contrast sensitivity and the range of vision. Additionally, Weeber and Piers, (2012) state that the improvement in image quality is observed further when this correction of chromatic aberration is introduced along with correction of spherical aberration. The Tecnis Symfony IOL is based on this technology and an early study of this lens by Pedrotti et al., (2016) found that this extended depth of focus IOL produced better distance, intermediate and near vision than an aspheric monofocal IOL. The IOL also produced similar visual quality when compared to the monofocal IOL. Another study, outlined that the Tecnis

Symfony IOL provided excellent visual restoration and that 91% of patients would recommend the same procedure (Cochener, 2016). Another extended depth of focus has since been introduced, the AT Lara 829MP (Carl Zeiss Meditec AG). To my knowledge there are no peer reviewed articles on this new IOL.

### 1.10.2 Accommodating intraocular lenses

Further to diffractive, refractive or a combination of refractive and diffractive multifocal IOLs is the accommodative IOL. Accommodative IOLs use the ciliary muscle to alter the position of the IOL thereby changing the focal length which results in most of the incoming light focused on one focal point. Single-optic accommodating IOLs create multifocality through contraction of the ciliary muscle causing forward movement of the IOL. It is believed that the degree of accommodative effect with such IOLs depends on the degree of IOL displacement and the power of the displaced IOL (Mcleod et al., 2007). A high-plus power combined with a stationary minus lens should provide consistent and greater magnitude of accommodative power. Dual-optic accommodating IOLs therefore utilise the concept of a high power plus lens coupled with a stationary minus powered lens. While this is similar to a Galilean telescope there are some important differences. The dual-optic accommodating IOL produces vergence in the range of +15 D to +30 D in contrast to the Galilean telescope that produces no vergence (Gooi and Ahmed, 2012). One drawback of dual-optic accommodating IOLs is that magnification leads to aniseikonia, difference in perceived image size, if the fellow eye remains phakic or is fitted with a single-optic accommodating IOL (McLeod et al., 2007). However, a study with the Synchrony (Abbott Medical Optics), a dual-optic accommodating IOL, found that the image magnification is limited to 2.5% which is within the tolerance level of patients before aniseikonia is noticed (Mcleod et al., 2007). Furthermore, it has been suggested by Hancox et al., (2006) that the movement of the lens is not sufficient to provide adequate near vision with accommodating IOLs.

Newer designs of accommodating IOLs are currently under trial. Such IOLs include the Fluidvision (Powervision, Inc.) IOL which is designed to mimic the eye's natural accommodative process by the movement of fluid inside the IOL in response to the eye's normal forces. This IOL is made from hydrophobic acrylic material which is filled with a silicone oil. When the accommodative forces of the eye act on the haptics of the IOL the silicone oil is pushed through the optic and the front surface of the IOL changes shape and increases in power (Kohl et al., 2014). Another accommodating IOL currently under trial is the Sapphire Autofocal IOL (Elenza). This IOL provides accommodation through the activation of an electroactive liquid crystal within an aspheric monofocal IOL. The IOL contains photosensors which monitor the change in pupil diameter with accommodation and therefore activates the liquid crystal (Ford et al., 2014).

### 1.10.3 Pseudophakic monovision correction

Another option to provide spectacle independence following cataract extraction surgery is through pseudophakic monovision correction. This methodology includes providing 2 images through binocular vision, where one eye is targeted to provide distance vision and in the fellow eye to provide near vision. This method has been used widely in contact lens correction, and in 1984 Boerner and Thrasher,

(1984) described this methodology in IOL use. It has been found that monovision correction with IOLs provides a high level of patient satisfaction with one study reporting 90% of patients reporting to be either highly satisfied or satisfied with the outcome of the treatment (Greenbaum, 2002). When utilising pseudophakic monovision one has to decide how much myopia will be targeted in the near vision eye. Traditional monovision often targeted a myopic refractive error between -2.00 to -3.00 D. However, it has been found that this level of anisometropia affects contrast sensitivity, stereopsis, and overall patient satisfaction (Handa et al., 2004; Wright et al., 1999). Therefore, often in pseudophakic monovision correction a modest amount of myopia is target (-1.00 to -1.50 D) and a study by Finkelman et al., (2009) outlined that patients who were targeted for a modest amount of myopia in their near vision eye achieved good distance and near vision, with good contrast sensitivity and stereopsis outcomes. Additionally, the mean satisfaction score out of 10 was 9.54 (range 8-10).

## 1.11 Refractive lens exchange

Many patients are now opting to negate the need of visual correction from either glasses or contact lenses by undergoing refractive surgery. It has been found that the disadvantages of glasses or contact lens correction has contributed to the rise in refractive surgery procedures (Bourque et al., 1984; Khan-lim et al., 2002). Refractive surgery was first suggested by Hermann Boerhaave in 1708 (Boerhaave, 1746). Boerhaave suggested that the lens could be removed through couching the non-cataractous natural lens, however it was not for many years until the first procedure was performed. Refractive surgery regarding the natural lens was first reported in literature by Vincenz Fukala who extracted the lens to improve visual acuity in the 1890s (Alió et al., 2014). Fukala only operated on children or adults up to the age of 40 who had poor sight or inability to work because of their vision due to myopia. The procedure included removal of the lens and washing out of the lens material (Alió et al., 2014). This procedure was met with opposition and it was recognised that in most cases the patient suffered a retinal detachment postoperatively, and refractive surgery was therefore mostly abandoned (Alió et al., 2014). However, the vast improvements in cataract treatment in the 20th century has resulted in the concept of refractive surgery again. The introduction of the IOL and the major advances in cataract treatment have now provided a safe and predictable method of correcting refractive error, which has resulted in the expectation of good postoperative uncorrected visual acuity. The development of multifocal IOLs has provided the surgeon with a lens that can achieve complete spectacle independence in many cases. Therefore, IOL implantation can be performed on individuals who wish to negate the requirement of spectacle correction but do not have cataract. This procedure is called refractive lens exchange (RLE). RLE is often the procedure of choice for patients who are presbyopic, and it has successfully been used to treat emmetropic presbyopes (Hoffman et al., 2003).

### 1.11.1 Alternative refractive procedures

Corneal refractive surgery is also available to patients who wish to negate the need for spectacles. The first suggestion of corneal refractive surgery was by Snellen, (1869), and since then corneal refractive surgery has developed greatly. In the mid

1900s radial keratotomy was introduced, and then lamellar surgery was introduced by Barraquer, (1949). However, the greatest advancement in corneal refractive surgery was observed with the introduction of the excimer laser to correct refractive error in the 1980s (McAlinden, 2012). Corneal refractive surgery has developed greatly and modern corneal refractive procedures are now widely performed. One such modern corneal refractive procedure is Laser in situ keratomileusis (LASIK), which involves creating a corneal flap followed by excimer laser ablation. A longterm study of LASIK outlined that 73% of eyes were within ±1.00 D and 92% were within ±2.00 D, and a mean mypopic regression of -0.12 D ± 0.16 was observed per year (Alio et al., 2008). Another, modern procedure is Laser-assisted subepithelial keratomileusis (LASEK) where the corneal epithelium is loosened using a dilute alcohol solution and then brushed to the side to perform laser ablation to the stroma. Claringbold, (2002) found that LASEK provided good postoperative vision. Furthermore, no eye lost corrected distance visual acuity (CDVA) and no eye required retreatment. The latest generation of laser corneal surgery is small incision lenticule extraction (SMILE) where an intrastromal lenticule is taken out through a small corneal incision. A study compared the outcomes of LASIK and SMILE where it was found that both procedures were safe and effective, however the SMILE procedure showed a lower rate of higher order aberrations (Lin et al., 2014). Corneal laser refractive procedures can be used to treat ametropia and presbyopia. Presbyopia can be treated using the monovision technique or a micro-monovision technique where spherical aberration is used to provide depth of focus (Reinstein et al., 2009; Reinstein et al., 2011; Reinstein et al., 2012).

Another method to treat ametropia are corneal inlays which were first described by Barraquer in 1949 (Barraquer, 1949). Early treatments with corneal inlays had various issues however the improvement in design and material has led to new corneal inlays. One modern corneal inlay is the KAMRA (AcuFocus Inc, Irvine, California) which is inserted under a LASIK flap into the corneal stroma. A study regarding the KAMRA corneal inlay for treatment of presbyopia showed that the inlay improved near vision without affecting distance vision or contrast sensitivity (Waring, 2011).

### 1.12 Subjective assessment of cataract and RLE patients

#### 1.12.1 Importance of subjective assessment

As outlined, cataract surgery or RLE with implantation of an IOL provides excellent postoperative objective visual performance. Objective clinical tests, such as visual acuity testing and contrast sensitivity, are routinely performed in ophthalmology clinics to assess the performance of these treatments. The main purpose of cataract surgery is to improve objective visual performance, and the main purpose of RLE is to provide spectacle free vision, and this change in visual status for both patient groups should consequently enhance a patient’s perception of their vision and provide high patient satisfaction. However, an individual’s perception of their vision and ultimately their satisfaction is dependent on their own observed problems, and is therefore subjective in nature. It is now recognised that objective assessments only provide an indication of how an individual actually perceives their vision (McGhee et al., 2000). For example, a patient may have poor postoperative visual acuity however this may satisfy their needs in everyday life and the patient may report to be happy with the outcome (Desai et al., 1996). To accurately assess this, subjective assessment where the patient is directly asked regarding the perception of their vision is required. Subjective assessment has not always been recognised as an independent measure because the level of visual acuity achieved was considered to indicate a patient's visual perception (Desai et al., 1996). However, it is now recognised that patients can have similar objective visual acuity but perceive their vision very differently (McAlinden et al., 2010). Therefore, it is important to ask each patient directly how they perceive the outcomes of their treatment to determine if the patient's needs are fulfilled. Studies reporting the outcomes of treatments such as cataract surgery should assess both objective and subjective measures (Javitt et al., 1993).

### 1.12.2 Subjective assessment method

Subjective assessment is performed through patient reported outcomes (PROs), usually in the form of questionnaires. Questionnaires are often referred to as instruments in literature. Along with the standard objective clinical tests questionnaires are widely utilised in the assessment of various medical techniques and interventions. Questionnaires provide a more holistic view on many health-related conditions and highlight the impact they have on an individual's subjective perception of their vision, and in many cases, are a requirement in clinical trials (Pesudovs et al., 2007). Vision-related questionnaires are utilised following refractive surgery, cataract surgery, with contact lens or spectacle patients, and in many other cases. Such questionnaires measure various subjective aspects, such as difficulties in performing daily-life activities, visual disability and visual function.

## 1.13 Questionnaire development

### 1.13.1 Traditional questionnaire development methodologies

The methodology used to develop vision-related questionnaires is important and has changed over the years. To develop a quality questionnaire there are fundamentally two aspects that should be considered. Firstly the content of the questionnaire must be developed meticulously and secondly, thorough analysis of the psychometric properties of the test should be adequately completed (Khadka et al., 2013). The psychometric properties refer to the assessment of the reliability and validity of the questionnaire.

Massof and Rubin, (2001) outline the traditional methods of questionnaire development. The initial step in questionnaire development should include an interview with a sample of patients thought to represent the intended target population in order to gain an understanding of the perception of the visual function and complaints within that target population. This provides a range of questions that are deemed suitable to investigate the subjective trait. The individual questions are referred to as items and in the early stage of development there are usually too many items, and the opinion of experts within the field is sought to refine the number of these items (Massof and Rubin, 2001). The items are then designed to be answered in two possible ways, either dichotomously or polytomously. The dichotomous responses have two possible answers, such as yes / no or true / false, and polytomous responses have a range of ordered responses, such as not at all / a little / quite / very (Massof and Rubin, 2001). Once the content of the questionnaire is decided the items are then grouped into different domains. Massof and Rubin,

(2001) explain that this is either completed on the developers' judgement, principal components analysis, or by a combination of the developers' judgment and confirmatory factor analysis. These analyses determine correlations of items and the number of variables the instrument assesses. A high correlation represents the same variable and if the items are uncorrelated they are assumed to assess different variables. Principal components analysis (PCA) is a variable reduction technique which reduces the number of variables to a smaller number of principal components that account for the observed variance in items. The number of components equals the number of variables found. The first component represents the most variance and the second component the second most variance in the data, and this pattern continues until all the variables are accounted for. It is considered that a variance greater than 60% shows a low possibility of further components across the data (McAlinden et al., 2010). Factor analysis describes the variance of the items within the questionnaire, and therefore shows which items group together around one factor (de Boer et al., 2004), and determines how many factors are measured. Factor analysis highlights items that do not fit the trait under investigation, where items with a value of <0.40 can be removed, and items that are redundant with a value of >0.80 can be removed (Pesudovs et al., 2007). Once the items are grouped together the responses are scored. The scoring of the early questionnaires is achieved through traditional tests such as the classical test theory (CTT). The basis of CTT is a simple summary scoring method. The score is produced by assigning the response categories of the questions an ordinal score and then the scores across the instrument are summed. This overall score, called the raw score, is assumed to represent the underlying trait (Pesudovs, 2006).

The next step in questionnaire development is to determine if the instrument truly measures what it is designed to measure. This is referred to as the validity of the instrument. Massof and Rubin, (2001) outline that this includes construct-related, content related, and criterion-related validation. Firstly, construct-related validation measures that the score produced by the instrument truly represents the trait under investigation, and this is commonly assessed by PCA and intercorrelations. Content-related validity provides information on the internal consistency of selected items. An example of a statistical test used to assess internal consistency is the Cronbach's alpha. Cronbach's alpha determines the correlation of the items to all other items (Pesudovs et al., 2007) and items that are redundant can be highlighted and removed from the instrument. Cronbach's alpha is expressed as a number from 0 to 1 (Tavakol and Dennick, 2011), with 0 representing no consistency in measurement and 1 representing perfect consistency. A value of >0.70 represents that 70% of variance in the scores is reliable variance. Therefore, a value of >0.70 is considered to be an acceptable value. As outlined, 1 represents perfect consistency however because Cronbach's alpha is essentially calculated by the average of the correlation coefficients between items, a value of >0.90 may represent redundant items (Pesudovs et al., 2007), which should subsequently be removed. Thirdly, criterion-related validation shows that the questionnaire is sensitive and specific enough to be used as a measure through comparison to a gold standard measurement (Massof and Rubin, 2001). This assesses that the newly developed instrument is correlated with a related construct, for example an instrument to assess visual acuity limitation should be correlated against objective visual acuity measures (Pesudovs et al., 2007). Pesudovs et al., (2007) also note that there should not be a very high (>0.90) correlation because this may represent that the new instrument does not provide any additional information. This analysis can be achieved through correlation tests, such as Spearman's correlation.

Assessment of the validity of the instrument is essential in questionnaire development but assessment of its reliability is also required, because if the instrument is unreliable it detracts from the validity of the instrument (Pesudovs et al., 2007). Reliability measures are important to show that the test is reliable across different administration conditions and the final questionnaire score produced is consistent when repeated (Massof and Rubin, 2001). Reliability is often assessed by Cronbach's alpha analysis, however as discussed above Cronbach's alpha is used to assess internal consistency opposed to reliability, and should not be overemphasised as a suitable method (Pesudovs et al., 2007). Other methods for reliability assessment include Pearson product-moment correlation coefficient, intraclass correlation coefficient, Kappa statistics or Bland-Altman limits of agreement (LoA). Intraclass correlation coefficient is a measure of agreement and is defined as the ratio between-groups variance and the total variance (Pesudovs et al., 2007). Kappa statistics are used with nominal data and determines the agreement between two measures of the same scale. The LoA is used to assess the agreement between two instruments with the same measurement units. However, if interpretation of the scale is unfamiliar to the clinician they may not be able to distinguish if the result is good or bad, which is a limitation of this method as outlined by Pesudovs et al., (2007).

The first questionnaire developed for use with cataract surgery patients was introduced in 1992 (Lundström and Pesudovs, 2011) and many subsequent questionnaires have been developed. An example of a questionnaire that was developed using traditional methodology to assess cataract patients is the Activities of Daily Vision Scale questionnaire (Mangione et al., 1992). This questionnaire was developed by highlighting various activities commonly performed by cataract patients. The questionnaire included 20 visual activities over five subscales. These included distance vision, near vision, glare disability, night driving and day driving. Each of the activities were given an ordinal response and the subscales were then scored from 0-100, with 0 representing inability to perform the task due to visual difficulty and 100 representing no visual disability (Mangione et al., 1992). The internal consistency was measured by the Cronbach's alpha and the content validity by PCA. Furthermore, Spearman's correlation was used to compare the item responses to binocular vision and the two global rating scales within the instrument to assess criterion validity. The authors conclude that this questionnaire is reliable and provides a valid measure of patients' subjective perception of visual impairment.

The development of a questionnaire requires expertise in the field and various tests to ensure that the instrument is accurate and truly measures what it is designed to measure. However, it is now widely acknowledged that the traditional methods for the development of vision-related questionnaires are limited. The fundamental shortcoming with the traditional development methodologies is that they do not display the properties required for measurement (Wright and Linacre, 1989). Mallinson, (2007) outlines that the traditional methods focused on internal consistency and validity, as outlined above, instead of the essential properties of measurement which include hierarchical order, equal interval and unidimensionality.

Hierarchical order is important for a proper measurement because it provides information on a dimension from less to more; when a measurement of length is taken, a smaller measurement represents a smaller distance (Mallinson, 2007). This concept is also important in the measurement of visual function because individuals have different levels of visual function and certain everyday tasks require different levels of visual function to complete. For example, reading small print does not require the same level of visual function as watching television. In the traditional methodologies, all items within an instrument are assumed to reflect the same amount of the trait under investigation. Mallinson, (2007) gives the example of two patients, where one patient reported to be able to recognise faces and drive, and another patient reported to be able to recognise faces, drive, cook and play games. If a point was given for each task they can fulfill as seen in the traditional methodologies (summary scoring), the first individual would score 2 and the second patient would score 4. It is assumed that the second patient has twice the visual function as shown by the raw scores however the activities they report to be able to do are similar. Therefore, it is hard to conclude that the second patient has twice the visual function as the first patient. However, traditional methodologies do not take this into consideration as the different items are considered to be the same difficulty and therefore the responses to items are given the same score, despite an item requiring a higher level of visual function than another (Mallinson, 2007). The second property for correct measurement is equal interval. This becomes evident in questionnaires when one considers the ordinal responses usually included in an instrument. An example of the ordinal responses often found in a questionnaire are: not at all, a little, quite, or very. It considers that these ordinal responses represent different levels of visual function with a patient who reports “not at all” having a superior visual function that a respondent who reports “very” to the same item. In traditional methodologies it is assumed that the visual function step between each category is equal, however this is indeed erroneous (Mallinson, 2007). The visual function of a patient who reports to be “very” bothered by recognising faces in the distance is significantly different to a patient who reports to be “very” bothered by reading small print. However, with traditional methodologies this was considered to be the case. Additionally, equal interval is important when considering a change in visual function across the whole scale. A change in visual function at the lower end of the scale represents a larger change compared to in the middle of the scale when using raw data as described by Mallinson, (2007). Thirdly, the trait under investigation must be unidimensional. If the items do not contribute to a unidimensional trait the measurement becomes meaningless. A patient may have a good score for one trait and a poor score for another trait, and the opposite may be true for a separate patient but both patients produce the same score. This is misleading because the two individual patients have subjectively reported the same score but for different traits (Mallinson, 2007). Cronbach’s alpha which is a measure of the internal consistency of the items has traditionally been used to assess the unidimensionality of instruments, however it has been outlined that Cronbach’s alpha is not independent of the number of items within the test (Massof, 2002). This can affect the outcome of the test and Cronbach’s alpha should therefore now be consider a traditional method rather than a useful measure (Pesudovs et al., 2007).

To achieve a meaningful measure of subjective outcomes the properties for measurement must be followed. In the everyday clinical setting, many objective tests are carried out to assess the visual performance of a patient, such as visual acuity or intraocular pressure, and the clinician knows that a lower score in one of these tests represents an objectively inferior visual performance. However, from the traditional questionnaire development this cannot be achieved for the subjective trait under investigation because traditional methodologies do not encompass the required properties for a measurement of a single trait. The above measures are essential for proper measurement to allow the scores produced by questionnaires to be additive or linearly related to a unidimensional trait under investigation.

### 1.13.2 Current questionnaire development methodologies

It is only within the last two decades that an emphasis has been put on the measurement properties of a questionnaire, and due to the shortcomings of the traditional methodology alternative approaches have been introduced. The item response theory (IRT) where persons and items can be scaled in relation to the responses of a group of people to items has been accepted as an alternative approach (Lundström and Pesudovs, 2011). IRT assumes that each visual symptom item within the questionnaire represents some level of the trait, and the items vary in difficulty and to answer the items correctly requires different levels of ability (Massof, 2002). The current most advocated approach in questionnaire development is Rasch analysis which displays many of the same theoretical principles as IRT but was developed independently. Rasch analysis was developed by Danish mathematician Georg Rasch in the late 1950s (Rasch, 1961) and was introduced to assess psychometric properties of intelligence or attainment tests most commonly in the educational setting. At its inception, the Rasch model was used to assess individuals through tests consisting of several items where the answers to the items were known and there was an expected pattern. Individuals who were found not to follow the expected pattern were considered to either be guessing or were careless with their answers. Additionally, if the items of the test deviated from the expected pattern they were considered not to contribute to the assessment and were discarded. The Rasch model is developed on the assumptions that the difficulties of the items are constant across the population and the abilities of the respondents are constant across all the items. This was termed "specific objectivity" by Rasch (Rasch, 1961). Therefore, the Rasch model is based on a probabilistic relationship between person ability and item difficulty. This is illustrated in figure 8 where the single black line represents the construct being investigated and the items (*d*) within the test are positioned in order of increasing difficulty.

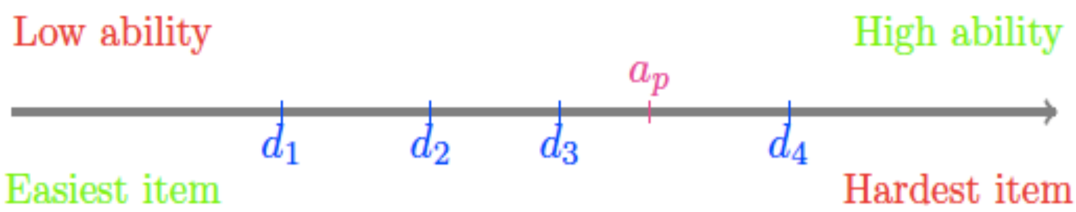


**Figure 8** Rasch measurement schematic. The trait under investigation is represented by the single black line with low ability / easiest item on left and high ability / hardest item on right. A respondent with ability $a_p$ is shown on the line and the probability of the respondent answering certain items correctly can be predicted.

Each item along the trait displays the probability of the respondent correctly answering each item, dependent on the person's ability. A respondent with an ability $a_p$ is also notated on this line in figure 8. This respondent is expected to score 3 because the respondent's ability is above the first three items, and it is expected that the respondent can answer correctly the items below their ability. It can also be assumed that this respondent in figure 8 will not be able to answer the last item on the line because it is above their ability. The Rasch analysis is fundamentally based on these probabilities and the main purpose of the model is to estimate the location of an individual with a certain ability on a line defined by the difficulty level of the items within a test. The probability of answering an item is expressed as a function of the size of difference between person ability and item difficulty. This is achieved by the conversion of the raw scores collected by a test into odds of success, which represents the ratio of the probability of being able to answer the item to not being able to answer the item. This creates a linear relationship between the dimension and the instrument. Then taking the natural log of this ratio the person ability estimate and the item difficulty estimate can be calculated, which is expressed on a logit scale (McAlinden et al., 2010). This transformation of the odds ratio using the natural log will produce values from negative to positive infinity, which are called logits. Positive logits represent a higher than average probability of endorsing items, and negative logits represent a lower than average probability of endorsing items. This transformation turns the raw data obtained for the test into continuous interval data providing a linear relationship between raw scores and the underlying trait being investigated.

An assumption of the Rasch model is that the trait under investigation is unidimensional and misfit statistics are utilised to determine the dimensionality of the instrument. This displays if the items of the test fit the model and if indeed the trait under investigation is unidimensional. Misfit statistics include infit and outfit statistics which are based on standardised residuals. Infit statistics detect unexpected patterns of answers by individuals on items that are targeted for them, and unexpected observations on items that are targeted for individuals. Outfit statistics detect unexpected answers from patients on items that are too easy or too hard for them, and vice versa. This provides information on the ability of the items to investigate the unidimensional trait under investigation.

Boone, (2016) describes various considerations required when planning to develop a test using Rasch analysis. The items must be devised to represent low, middle and high difficulty, and then some prediction of the location of the items along the line representing the trait under investigation should be made. This should be devised through the developers knowledge and current literature (Boone, 2016). Then following the careful construction of the items pilot data should be collected and analysed using Rasch analysis and then refined, as outlined above.

The Rasch model was first used for intelligence and attainment test in the educational setting, however it was soon recognised as a valid methodology for the development of questionnaires. The benefits of Rasch analysis were realised as it allows a meaningful measurement of the trait under investigation through the transformation of raw ordinal scores into a linear interval scale. Hence, the wide use of the Rasch model in vision-related questionnaires (McAlinden et al., 2011b; Khadka et al., 2010). In contrast to the traditional summary scoring method a meaningful measure can be achieved through Rasch analysis because, firstly, it provides hierarchical order as it presents a probabilistic relationship between person ability and item difficulty and allows items to be arranged from easiest to hardest, allowing a meaningful comparison between patients. Rasch analysis fulfills the second requirement for proper measurement, equal interval, as Rasch analysis constructs the data into a linear scale allowing one to more easily compare patient outcomes at different times and different cohorts of patients. The third feature of measurement is unidimensionality (Mallinson, 2007), and through the model and item fit statistics Rasch analysis provides information on dimensionality (Pesudovs et al., 2007). It is important that a questionnaire is found to represent one single underlying trait because if there is more than one trait being investigated the meaning of the questionnaire becomes unclear (Pesudovs et al., 2007), as outlined previously.

Rasch analysis is currently the most advocated approach for vision-related questionnaire development because it fulfills the requirements for measurement and provides a meaningful measure of subjective outcomes (Wright and Linacre, 1989). Subsequently, many vision-related questionnaires have been developed by Rasch analysis (Pesudovs et al., 2006; Gupta et al., 2007; Pesudovs, 2004) and many questionnaires have been re-validated using this model (Pesudovs et al., 2003; Pesudovs et al., 2008; Lamoureux et al., 2008).

The Activities of Daily Vision Scale questionnaire which is outlined above was developed using traditional methodology and was found to be reliable and a valid assessment of the visual impairment (Mangione et al., 1992). However, Pesudovs et al., (2003) re-evaluated this questionnaire using Rasch analysis and found that the response categories should be shortened to three responses, and poor targeting of item difficulty to person ability and that the item number could be reduced. Pesudovs et al., (2003) concluded that despite thorough development of this questionnaire with traditional methods the current most advocated approach of questionnaire development exposed inadequacies of this frequently used questionnaire.

### 1.13.3 Quality Criteria for questionnaire development

There is now a vast number of vision-related questionnaires available. In 2006 Pesudovs et al., (2006) reported that there are more than 70 questionnaires for visual function, 24 QoL instruments and hundreds of disease specific questionnaires in existence. Due to the wide range of questionnaires available it can be difficult for practitioners to determine which questionnaire to use and if the instrument has been developed adequately. Therefore, studies have been published to outline the quality criteria required for the production of questionnaires in line with the current literature (Terwee et al., 2007; Pesudovs et al., 2007; de Boer et al., 2004).

The use of Rasch analysis is advocated in these studies to inform clinicians that vision-related questionnaires should now be developed by Rasch analysis, because the summary scoring methods produce noise and reduce the sensitivity of the questionnaires (Khadka et al., 2013). Furthermore, a questionnaire should have a clear definition of the target population and the purpose of the instrument. When the target population is determined, it is then important that the instrument is developed on a similar cohort of patients to ensure that the relevant content is included. The language should be simple, brief and avoid intellectualisation (Pesudovs et al., 2007). It is important that the items within the questionnaire reflect the trait under investigation, and focus groups with the target population should be completed to ensure relevance and content validity, because it is the patients' subjective opinion the instruments are attempting to assess (de Boer et al., 2004). Additionally, one-to-one interviews with experts within the field and reference to published literature are important to further enhance the content validity and relevance (Pesudovs et al., 2007).

Subjective assessment is an essential aspect of clinical assessment and provides valuable information into the perception and satisfaction of patients, which cannot be assessed through objective clinical tests. It is now well acknowledged that traditional development methods are inadequate and the current most advocated approach of Rasch analysis overcomes many of the shortcomings of traditional development methods. It is important that questionnaires are developed accurately and the outcomes they produce are meaningful to allow the accurate assessment of interventions and treatments.

### 1.14 Quality of vision questionnaire

A questionnaire that has been developed to be used in the clinical setting is the QoV questionnaire (McAlinden et al., 2010). Quality of vision (QoV) is described by McAlinden and Moore, (2010) as a subjective entity that is based on the patient's unique perception of their own vision and consists of both visual and psychological factors. Subjective assessment of QoV following cataract extraction surgery is essential to truly determine how an individual perceives their vision. A patient may perform very well with the objective tests however they may not be satisfied with the outcome, or two patients may have identical objective outcomes and yet perceive their vision very differently. Therefore, it is important to assess a patient's perception of his or her QoV. To adequately assess QoV following cataract extraction surgery a validated questionnaire is required. McAlinden and Moore, (2010) explain that many questionnaires include QoV questions but that this is in conjunction with other latent trait questions, such as visual disability. Questionnaires must investigate the same trait otherwise the meaning of the assessment is unclear. Therefore, this QoV questionnaire was developed to be used with patients undergoing refractive surgery, cataract extraction or refractive correction with spectacles or contact lenses. In the development of this questionnaire, a wide knowledge was obtained through an extensive literature search and interviews with experts and non-experts were completed to identify items that should be included. Ten symptoms were selected and it was decided that each item should consists of a frequency, severity and bothersome component therefore creating a 30-item questionnaire. The first 7 symptoms were accompanied by pictures to aid understanding. Rasch analysis was performed on the ten items relating to frequency, severity and bothersome separately. To assess unidimensionality of the instrument misfit statistics and PCA were performed. The questionnaire provides scores ranging from 0 – 100, with a higher number representing worse QoV. The QoV scores were compared to visual acuity, contrast sensitivity and HOAs to assess construct validity. Additionally, 20 subjects were invited to repeat the instrument 10 days later. This QoV has been utilised in various studies (Skiadaresi et al., 2012; McAlinden et al., 2011b) and has been found to provide an accurate assessment of QoV, and is a reliable and valid instrument for the assessment of cataract patients and refractive surgery patients.

### 1.15 Summary

From the first IOL implantation in 1949 by Harold Ridley, IOL design and optics have developed greatly. The initial work with the IOL was met with widespread criticism from many surgeons at the time, however IOL implantation following cataract extraction surgery or RLE is now the most common medical procedure performed. The advancements in many aspects of surgical procedure, including small incision surgery and phacoemulsification, has made cataract extraction surgery with subsequent IOL implantation a very safe and predictable procedure. Additionally, the development of the multifocal IOL since its first introduction in the late 1980s has provided not only an improvement in QoL following the removal of the cataractous lens but also the option of complete spectacle independence. Rotationally asymmetric multifocal IOLs are now commonly used however the various preoperative considerations such as placement and near add power used has not been fully investigated, and further optimisation of postoperative outcomes may be possible.

Subjective assessment of visual function is now widely recognised as an important aspect of clinical assessment following IOL implantation, and the development of questionnaires to assess such outcomes have changed and developed since their first use. Subsequently, many instruments have been produced in attempt to provide an accurate insight into patients' subjective visual function. The development of reliable and valid questionnaires to assess postoperative outcomes is essential.

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## 2. PAPER-I

**An alternative application of Rasch analysis to assess data from ophthalmic patient-reported outcome instruments**

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**Contributions**

Richard N. McNeely – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Salissou Moutari – *concept and design, data analysis/interpretation, drafting manuscript, critical revision of manuscript, statistical analysis*

Samuel Arba-Mosquera – *data analysis/interpretation, critical revision of manuscript, statistical analysis*

Shwetabh Verma – *data analysis/interpretation, critical revision of manuscript, statistical analysis*

Jonathan E. Moore – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis, supervision*

**An alternative application of Rasch analysis to assess data from ophthalmic patient-reported outcome instruments**

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## ABSTRACT

**Purpose:** To highlight the misuse of Rasch analysis for validation of ophthalmic questionnaires, and to present an alternative application of Rasch analysis to derive insights specific to the cohort of patients under investigation.

**Methods:** An alternative application of Rasch analysis was used to investigate the quality of vision (QoV) for a cohort of 481 patients. Patients received multifocal intraocular lenses and completed a QoV questionnaire one and twelve months postoperatively. The rating scale variant of the polytomous Rasch model was utilised. The parameters of the model were estimated using the joint maximum likelihood estimation (JMLE). Analysis was performed on data at both postoperative assessments, and the outcomes were compared.

**Results:** The distribution of the location of symptoms altered between assessments with the most annoyed patients completely differing. One month postoperatively, the most prevalent symptom was starbursts compared to glare at twelve months. The visual discomfort from the most annoyed patients is substantially higher at twelve months. The current most advocated approach for validating questionnaires using Rasch analysis found that the questionnaire was "Rasch-valid" one month postoperatively and "Rasch-invalid" twelve months postoperatively.

**Conclusion:** The proposed alternative application of Rasch analysis to questionnaires can be used as an effective decision support tool at population and individual level. At population level, this new approach enables one to investigate

the prevalence of symptoms across different cohorts of patients. At individual level, the new approach enables one to identify patients with poor QoV over time. This study highlights some of the flaws associated with the current use of Rasch analysis to validate questionnaires.

## 2.1 INTRODUCTION

The concept of patient-reported outcome (PRO) measures borrowed from clinical trials have become nowadays a routine practice in ophthalmology. Patients are invited preoperatively and postoperatively to complete PRO instruments, most commonly questionnaires, whose data are used to gain more insight into the patient's subjective experience of vision-specific health-related problems as well as the impact of ophthalmic treatments on their quality of life. The overall aim of this exercise is to improve the clinical quality of care.

During the last decade, Rasch analysis has been used not only to assess and define the subscale structure of items within ophthalmic questionnaires (Gothwal et al., 2009a; Lamoureux et al., 2008; Lamoureux et al., 2006; McAlinden et al., 2010; Pesudovs et al., 2005; K. Pesudovs et al., 2007), but also to systematically dismiss the relevance of certain questionnaires solely on statistical grounds rather than substantive grounds (Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010; Khadka et al., 2012; Khadka et al., 2013; Lamoureux et al., 2009; McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009). However, the major shortcoming of such applications of Rasch analysis is the oversight on some fundamental assumptions enabling the key commendable features of the Rasch model as well as the intrinsic nature of the phenomena a questionnaire is attempting to measure.

Some of the most fundamental hypotheses, assumed by the Rasch model, include the homogeneity assumptions for both the test items (the questionnaire in this case) and the population of interest (the patients in this case). These two assumptions have been instrumental in the derivation of the Rasch model. Indeed, they enable the decomposition of the probability of item responses into two independent components, namely an item-specific difficulty parameter, which is constant across all the population of interest, and an ability parameter for each individual, which is identical across all the items in the test. This principle of invariant comparison was termed “specific objectivity” by Rasch (Rasch, 1961; Rasch, 1977).

The assumptions of homogeneity will not be met in sections of the data collected via ophthalmic questionnaires for various reasons. For instance, some or all of the items of the questionnaire may function differently in patient subpopulations, or the responses of patients to these items may depend on more than one underlying construct or latent trait. This could be problematic in particular when the questionnaires are completed by a population of patients from different backgrounds, for instance in terms of lifestyle or by the same population of patients at different time points. Since the response to the questionnaires are by nature subjective, the aforementioned eventualities may readily make them deviate from the assumption of "specific objectivity" (Rasch, 1961; Rasch, 1977), which is crucial for a proper application of the Rasch model. As a consequence, a so-called “Rasch validated” questionnaire for a given cohort of patients and a given latent trait may not be “Rasch-valid” for another cohort of patients with the same latent trait, or for the same cohort of patients with the same latent trait at a different time point. The approach currently advocated for validating ophthalmic questionnaires is entirely based on the analysis of fit of the Rasch model on data from a single potentially non-representative cohort of patients, occasionally with a relatively small sample size (Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010; McAlinden et al., 2011; Huang et al., 2017; Khadka et al., 2011). However, it is well recognised that the analysis of fit for the Rasch model is a never ending process since a continued use of the instrument requires constant monitoring of the item and person responses to maintain quality control (Wright and Stone, 1999).

At its inception, the Rasch model aims to assess psychometric properties of some intelligence and attainment tests. In such context, individuals are examined via some tests consisting of several items for which the correct responses are objective and well known, and the responses are expected to follow some specific patterns. The Rasch model orders the items from the easiest to the most difficult item based on frequency, such that the easiest items are answered correctly more often and the more difficult items are less frequently answered correctly. The individuals misfitting the model correspond to those individuals whose responses deviated from the expected patterns and it could be envisaged that these responses are partially based on guessing or they are due to some carelessness from the respondents. On the other hand, the items misfitting the model correspond to those items which do not contribute to an adequate assessment of the examinees; henceforth it may be envisaged to discard these outlying items or questions from the test. However, in order to maintain quality control, a continuous monitoring of the item and person responses is necessary (Wright and Stone, 1999).

In the context of test-based ophthalmic instruments such as LogMAR or Snellen charts for visual acuity testing, the correct responses to the items are objective and well known. Furthermore, the responses are expected to follow some specific patterns and serious item misfit generally indicates an unanticipated problem which may be attributed to the quality of the items. However, for ophthalmic questionnaires which are based on items with subjective responses and are often independent, the misfitted items may be interpreted differently. For instance, a consistent difference in response propensity introduced by variation in the characteristics of the respondents such as lifestyle, age and gender may contribute significantly to item and/or person misfits. The misfitted items and / or persons therefore may not necessarily be outliers. Even if they were, medical care implies that patients are taken as individuals with their own problems, and not as a group. Further misfitting items likely to be discarded, may actually be relevant for the quality of care (although they may imply a different latent trait). In other words, Rasch validation as performed currently, might help qualify a technique or a therapy but it does not provide any insight into the cause of particular patients being affected differently by the same item.

In contrast with the current validation practice, which consists of using Rasch analysis to dismiss (Pesudovs et al., 2007; Finger et al., 2012; V. K. Gothwal et al., 2009b; Gothwal et al., 2010; Khadka et al., 2012; Khadka et al., 2013; Lamoureux et al., 2009; McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009) or approve (Konrad Pesudovs et al., 2007; Khadka et al., 2013; Khadka et al., 2011; Wright and Stone, 1999; Garamendi et al., 2006; Gothwal et al., 2009c; Khadka et al., 2016; Marella et al., 2010; Pesudovs et al., 2010) an ophthalmic questionnaire based solely on the misfit statistics of the items, this work introduces a novel, meaningful and relevant stratified approach of the Rasch model to analyse data collected via ophthalmic questionnaires. The proposed approach aims to present Rasch analysis as a decision support tool for deriving valuable insights specific to the cohort of patients under investigation, at both population and individual level. At the population level, such an approach enables the investigation of the prevalence of ophthalmic symptoms across different cohorts of patients preoperatively and postoperatively, in order to assess the effectiveness of a treatment, for example, different types of intraocular lenses (IOLs) or different surgical procedures. At the individual level, the new approach can be applied across a population at different time points and identify patients who experienced most visual discomfort preoperatively and / or postoperatively, so that additional appropriate care and monitoring can be dedicated to them. Ultimately, this new perspective will pave the way for a more adequate application of Rasch analysis within the context of ophthalmic questionnaires, so that insights gained from the analysis can be exploited to enhance the quality of care and patient care experience. However, this paper does not attempt to advocate an alternative method of validation of ophthalmic questionnaires, and our future work will investigate this aspect of ophthalmic questionnaire development.

The remaining part of this paper is organised as follows. Section 2 briefly presents the Rasch model and highlights the key mathematical features and their meaning. Then, a brief overview and illustration of Rasch analysis for dichotomous response data is provided. Section 3 presents an application of Rasch analysis on data from an ophthalmic questionnaire as an effective decision support tool for a postoperative follow-up of patients, at both population and individual level. The overarching aim of the process is to improve our understanding of how the subjective responses of patients evolve over time, which ultimately should provide the opportunity to improve the patient care experience. Finally, Section 4 concludes the paper and highlights some potential further research.

## 2.2 Background

In a series of seminal research works (Rasch, 1980; Rasch, 1961; Rasch, 1966; Gothwal et al., 2009a; Lamoureux et al., 2008; Lamoureux et al., 2006; McAlinden et al., 2010; Pesudovs et al., 2005; Pesudovs et al., 2007; Finger et al., 2012; Gothwal et al., 2009a; Gothwal et al., 2010; Khadka et al., 2012; Khadka et al., 2013; Lamoureux et al., 2009; McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009; Rasch, 1977) Rasch introduced a probabilistic framework for analysing the ability of pupils using a model for the items of a test, which is known as the Rasch Model. This section will briefly present a basic set of assumptions and the general framework that underpins the Rasch model from its original form to its most commonly used version, implemented in most of the software packages dedicated to Rasch Analysis.

The Rasch model formulation is based on a two-dimensional data matrix, denoted $U$, obtained by administering a test, which consists of $n$ items, to $m$ examinees or persons. Each component $u_{pi}$, of the matrix $U$, denotes the response of the examinee or the person $p$ to the item $i$. The response to the items, i.e. $u_{pi}$, can be dichotomously or polytomously scored hence the denomination *dichotomous* or *polytomous* Rasch model, respectively. The general form of the data matrix $U$ is shown in Table 1. The Rasch model (Rasch, 1980; Rasch, 1966) owes its key desirable mathematical features to a certain number of assumptions, and the most fundamental assumptions will be described in this section.

The fundamental assumptions behind the Rasch model are:

**Assumption 1** (Rasch, 1980; Wright and Stone, 1979) *The response of an examinee or a person p to an item i, $u_{pi}$, depends solely on the examinee's ability, characterised by the parameter $a_p$, and the difficulty of the item, characterised by the parameter $d_i$.*

Basically, the main purpose of a test is to estimate the location of an individual with a certain ability, taking the test, on the line defined by the difficulty level of the different test items (Wright and Stone, 1979). This is illustrated in Figure 1, where the ability of the person $p$ is between $d_3$ and $d_4$, which represent the difficulty level of items 3 and 4, respectively. Therefore, it is expected that the person $p$ will be able to answer correctly all the items with difficulty below his/her ability $a_p$. If the score for a correct answer to each item is 1, then the total expected score for the person $p$, from this test, is 3.

**Assumption 2** (Rasch, 1980; Rasch, 1966) *The ability and the difficulty characterise the person and the item, respectively, such that if an examinee p was k times as able as an examinee q then* $a_p = ka_q$. *Similarly, if an item i was k times as difficult as an item j, then* $d_i = kd_j$ *. Thus,*

$$\frac{a_p}{d_i} = \frac{a_q}{d_j}. \tag{1}$$

Using Equation (1) in Assumption 2, Assumption 1 reduced to the following.

**Assumption 3 (Unidimensionality)** *The response of an examinee p to an item i,* $u_{pi}$, *depends solely on the ratio* $a_p/d_i$, *denoted* $\xi_{pi}$.

Another key assumption behind the Rasch model is that:

**Assumption 4 (Specific objectivity)** (Rasch, 1966) *For any given set of items with some given difficulties and any population of examinees with some given abilities, the response of the examinees to the items are stochastically independent.*

This assumption considers that on the one hand, the response of some examinees with the same ability to the *n* items in the test are independent. On the other hand, the response of the examinees to an item with a given difficulty are independent. Thus, this assumption enables the Rasch model to treat the examinees and the items independently. However, this assumption is not always satisfied in practice.

### 2.2.1 Dichotomous Rasch model

If the responses to test items consist of only two categories then without loss of generality we can assume that the response of any examinee *p* to any item *i*, $u_{pi}$, can only be either 0 or 1. The dichotomous Rasch model estimates the probability of any instance of response $u_{pi}$ as:

$$P(u_{pi}|\hat{a}_p, \hat{d}_i) = \frac{e^{(\hat{a}_p - \hat{d}_i)u_{pi}}}{1 + e^{(\hat{a}_p - \hat{d}_i)}}, \tag{2}$$

where $\hat{a}_{p,}$ as the estimated ability of the person *p* and $\hat{d}_i$ is the estimated difficulty of item *i*. Some details on the derivation of the dichotomous Rasch model as well as its mathematical properties are presented in Appendix A.

### 2.2.2 Parameters estimation and goodness of fit measures for the Rasch model

**Estimating parameters of the Rasch model.** There are a variety of methods which can be used to estimate the set of parameters ($\hat{a}_p$, $\hat{d}_i$) of the Rasch model (2), see Linacre, (1999) and Linacre, (2004) for an overview. However, the most commonly implemented methods in software packages dedicated to Rasch analysis include the joint maximum likelihood estimation (JMLE) and the marginal maximum likelihood estimation (MMLE).

The JMLE procedure assumes some initial known estimates of the parameters of the persons and items, then uses Newton-Raphson iterations to improve jointly the estimates of parameters, until a specific convergence criterion has been satisfied. This approach requires the removal of items and persons with perfect scores (i.e. all their scores are either equal to one or equal to zero for the dichotomous model). The MMLE approach assumes a known distribution, of the persons' parameters, which is used to estimate the items' parameters. In contrast with the JMLE approach, MMLE enables estimation of the parameters of items and persons with all scores equal to one or zero. However, the reliability of the parameters estimated using the MMLE approach depend upon the relevance of the assumed distribution of the person parameters. Hence, the MMLE approach could be prone to greater bias compared to the JMLE approach.

**Measuring goodness of fit for the Rasch model.** The most commonly used goodness of fit measure for the Rasch model, i.e. how well the model fits the observed data, is to test the normality of residuals. Each residual represents a piece of information not covered by the model, and large residuals raise doubts about the match between the model and data (Wright and Stone, 1979; Wright and Masters, 1982). In Rasch analysis, the goodness of fit measures, also called misfits statistics, consist of the infit and outfit test statistics which are based on the standardised residuals. The outfit statistic, also referred to as outlier-sensitive fit statistic, is a measure that is sensitive to unexpected observations by persons on items that are very easy or very hard for them, and vice-versa. The infit statistic, also referred to as inliner-pattern-sensitive fit statistic, is a measure that is sensitive to unexpected patterns of observations by persons on items that are targeted for them, and vice-versa. The most commonly used misfit statistics for Rasch analysis are the Mean square (MNSQ) misfit statistics and z-standardised misfit statistics. Some details on the derivation of these statistics are provided in Appendix B. MNSQ fit statistics (Outfit MNSQ and Intfit MNSQ) describe the level of the randomness in the response data, and their expected values are 1. The values of MNSQ fit statistics which are very low compared to 1, indicate a high degree of predictability of responses to the items by the model, i.e. the model overfits the data. On the other hand, the values of MNSQ fit statistics, which are very high compared to 1, indicate a high degree of unpredictability of responses to the items by the model, i.e. the model provides a distorted representation of the data. A general guideline is that values of MNSQ fit statistics greater than 1.5 suggest a deviation of the model from the unidimensionality assumption within the data. The value 1.5 is rather a rough approximation of the z-score for an area of 0.95 (or 95%) for the cumulative function of the standard normal distribution, which is about 1.64. This means that 95% of the values of MNSQ fit statistics are generally below the threshold of 1.5 (or to be more accurate 1.64). On the other hand, values of MNSQ fit statistics less than 0.5 suggest an overfitting of the model.

The *z*-standardised misfit statistics describe the improbability of the model to fit the data, and their expected values are 0. The values of *z*-standardised misfit statistics which are very low compared to 0 (less than -1.9) indicate an overfitting of the model; on the other hand, the values of $z$-standardised misfit statistics which are very high compared to 0 (greater than 1.9) indicate that the model is less likely to fit the data. The $z$-standardised misfit statistics are generally used when the MNSQ statistics fail.

### 2.2.3 Polytomous Rasch Model

When the item response data have more than two response options, a generalised version of the Rasch model known as the polytomous Rasch model is used. The polytomous Rasch model inherits most of the properties of the dichotomous Rasch model. The main difference between these two models lies in the introduction of the concept of thresholds in the polytomous version. These thresholds play an important role for a polytomous model since they enable the identification of critical points along the latent trait continuum. Furthermore, for a polytomous model, each item response category has a unique probability distribution associated with it, and at a threshold the relative probabilities of two adjacent item response categories are equal.

There are two types of polytomous Rasch models commonly used in the literature. Namely, the Rating Scale Model (RSM) (Andrich, 1978), in which the threshold estimate, for a given category response, is identical for all the items, and the Partial Credit Model (PCM) (Masters, 1982), in which the estimates of the thresholds can vary across the items and response categories. The PCM model can be viewed as a generalisation of the RSM.

The RSM can be formulated as follows:

$$P(u_{pi} = \eta | \hat{a}_p, \hat{d}_i, \hat{h}_t) = \frac{e^{\sum_{t=0}^{\eta} (\hat{a}_p - \hat{d}_i + \hat{h}_t)}}{\sum_{\eta=0}^{k} e^{\sum_{t=0}^{\eta} (\hat{a}_p - \hat{d}_i + \hat{h}_t)}}, \tag{3}$$

where, $p = 1, \ldots, m$ denotes an examinee's index, $i = 1, \ldots, n$ denotes an item's index, $\eta = 0, \ldots, k$ denotes an item response category, and $t = 0, \ldots, k - 1$ denotes a threshold's index; the parameter $\hat{h}_t$ denotes the common threshold associated with all the items for the category response $t$, whereas the rest of the parameters are identical to those defined for the dichotomous model in the previous sections.

The PCM can be formulated as follows:

$$P(u_{pi} = \eta | \hat{a}_p, \hat{d}_{it}) = \frac{e^{\sum_{t=0}^{\eta} (\hat{a}_p - \hat{d}_{it})}}{\sum_{\eta=0}^{k} e^{\sum_{t=0}^{\eta} (\hat{a}_p - \hat{d}_{it})}}, \tag{4}$$

where $\hat{d}_{it}$ denotes the joint item difficulty and threshold parameter, while the remaining notations are identical to those in the RSM model (Rasch, 1966).

### 2.3 A brief overview and illustration of Rasch analysis for dichotomous response data

From the above sections, Rasch analysis can be summarised into the following three main steps:

Step 1: This step uses the data from the response matrix to estimate the initial values of the difficulty and ability parameters for each item and person, respectively;

Step 2: This step uses the initial parameters estimates, from Step 1, to obtain some optimal estimates of the difficulty of items and the ability of persons parameters;

the most commonly used techniques to achieve this include the JMLE and the MMLE;

Step 3: This step consists of the identification of items and persons with unexpected response patterns using goodness of fit measure, for example, MNSQ or *z*-standardised misfit statistics.

Steps 1 and 2 are often combined into a single step known as the calibration step, whereas the last step is generally termed the fit analysis.

### 2.3.1 Illustration of Rasch analysis to assess a LogMAR chart for visual acuity testing

In order to illustrate the aforementioned steps, we consider the following data matrix for dichotomous response where 10 patients undergo a visual acuity test using the 9 items LogMAR chart depicted in Figure 2. In the response data matrix, the score of 1 corresponds to a correct answer to an item (i.e. if at least 3 correct answers are given in a row of the chart) by a patient, whereas a score of 0 corresponds to an incorrect answer (i.e. if at most 2 correct answers are given in a row of the chart). In this situation, the concept of person ability and item difficulty, in the Rasch model, corresponds to the patient's location (in logit) in terms of visual acuity, and the item's location (in logit) in terms of difficulty to read. The higher the location of a patient (respectively, an item), the higher the visual acuity (respectively difficulty to read) of the patient (respectively for the item).

**Remark 1:** Due to the following conditions, Rasch analysis can be an appropriate approach for the assessment of a LogMAR chart for visual acuity testing:

1. for a LogMAR chart, the correct responses to items are objective and known;

2. the responses to the items are expected to follow specific patterns according to the patient's location, in terms of visual acuity, and the item's location, in terms of difficulty to read; for instance, a patient with a given location is expected to read correctly most of the items with lower locations, and the misfit statistics (e.g. Outfits and Infits MSNQ) enable the identification of any unexpected response patterns from a patient and for an item;

3. the scenario complies with the most fundamental assumptions behind the Rasch model (namely, Assumptions 1, 2, 3, and 4).

### 2.3.2 Step 1: Estimation of the initial locations for items and patients

In this step, the following rows and columns in Table 2 are calculated: columns $r_p, \mu_p, \hat{a}_p^0$ and rows $r_i, \mu_i, \hat{d}_i^0, \hat{d}_i^{0(Adj)}$, where

- $r_p = \sum_{i=1}^{n} u_{pi}$ and $r_i = \sum_{p=1}^{m} u_{pi}$ are the total score for patient *p* and item *i*, respectively;
- $\mu_p = \frac{r_p}{n}$ and $\mu_i = \frac{r_i}{m}$ are the proportions of the correct responses for patient *p* and item *i* respectively
- $\hat{a}_p^0 = \log\left(\frac{\mu_p}{1-\mu_p}\right)$ and $\hat{d}_i^0 = \log\left(\frac{1-\mu_i}{\mu_i}\right)$ are the initial estimates of the locations for patient *p* and item *i*, respectively;
- $\hat{d}_i^{0(Adj)} = \hat{d}_i^0 - \frac{\sum_{i=1}^{n} \hat{d}_i^0}{n}$, is the adjusted initial location for item *i*; thus the mean of the adjusted locations for the items is zero.

### 2.3.3 Step 2: Estimation of the optimal locations for items and patients

In this step, the initial estimates of the visual acuity location of each patient, $\hat{a}_p^0$, and initial adjusted estimates of the difficulty location of each item, $\hat{d}_i^{0(Adj)}$, are improved by maximising the likelihood of the response of each patient to each item to obtain the optimal patient's visual acuity location $(\hat{a}_p^*)$ and item difficulty location $(\hat{d}_i^*)$. The JMLE was used to obtain the optimal parameters $\hat{a}_p^*$ and $\hat{d}_i^*$.

### 2.3.4 Step 3: Identification of items and patients with unexpected response patterns

From the optimal locations results for items and patients, presented in Table 3 and Table 4 and depicted in Figure 3, the following observations can be drawn for this cohort of patients.

- The most difficult item to read was Item 9, followed by Item 7 and Item 8, whereas Items 2, 3, 4 were the easiest to read, followed by Items 1, 5, 6. Furthermore, since Items 2, 3, 4 have the same values for the location estimates, then the model suggested that these three items have the same degree of difficulty for this cohort of patients. Likewise, Items 1, 5, 6 have the same degree of difficulty for this cohort of patients.
- The patient with the highest visual acuity within the cohort was Patient 2, followed by Patient 1, 3, 4, 5, Patient 6 and Patient 7, whereas Patient 9, 10 had the lowest visual acuity, followed by Patient 8. Although Patient 2 did not answer Item

8 correctly, he/she is most likely to respond correctly to all the items, thus his/her location is higher than the location of the hardest item (Item 9). On the other hand, although Patients 9 and 10 responded correctly to two items, the erratic patterns in their responses suggest that they are less likely to answer correctly any of the items on the chart. Thus, the estimates of their locations are lower than the location of the easiest item to read.

- The relatively high Outfit MNSQ value, compared to 1, for Item 9 reflected the outlying response pattern for this item. In fact, only the patient with the highest visual acuity (Patient 2) and one of the patients with the lowest visual acuity (namely Patient 10) responded correctly to this item. This is a rather unexpected response pattern for Item 9.
- The relatively high Outfit and Infit MNSQ values, compared to 1, for Patient 10, highlighted the outlying patterns of his / her responses. Indeed, this patient answered correctly only one relatively easy item (Item 6) and the hardest item (Item 9), which is unexpected.
- The relatively high Outfit MNSQ value, compared to 1, for Patient 1, indicated that this patient only failed the hardest item (Item 9) and a relatively easy item (Item 1). The latter wrong response is rather unexpected.

## 2.4 Methods and patients

### 2.4.1 Application of Rasch analysis to assess data from an ophthalmic PRO instrument

Test-based ophthalmic instruments, such as visual acuity tests using Snellen or LogMAR charts, where the correct responses to the items are objective and well known, and the responses are expected to follow specific patterns, comply with the main assumptions behind the Rasch model. Therefore, the model can be used to assess whether these instruments are appropriate for their purpose. In such cases, serious item misfit generally indicates an unanticipated problem which may be attributed to the quality of the items. However, in the context of ophthalmic questionnaires, the responses are subjective by nature and as a consequence, some of the major assumptions of the Rasch model, namely Assumptions 3 and 4 presented in section 2 do not always fully hold. Due to the subjective nature of the responses to the items the misfit statistics may be interpreted differently. For instance, a consistent difference in response propensity introduced by various respondents' characteristics such as lifestyle, age and gender may contribute significantly to items and/or person misfits.

The currently most advocated practice, for validating ophthalmic PRO questionnaires, is either to collapse some item response categories or to drop items or questions which misfit the Rasch model (Gothwal et al., 2009d; Finger et al., 2012; Garamendi et al., 2006). If for any reason all the items misfit the model or some estimation problems are encountered during the process then the entire questionnaire is dismissed (Pesudovs et al., 2007; Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010; Khadka et al., 2012; Khadka et al., 2013; Lamoureux et al., 2009; McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009). However, even for tests based on items with objective and known responses it is well recognised that in order to maintain quality control, a continuous monitoring of items and patient responses is required (Wright and Stone, 1999).

The main objective of this study is to attempt to introduce an alternative application of Rasch analysis, which is specific to the cohort under investigation, as an alternative to the current misuse of the method to dismiss (Pesudovs et al., 2007; Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010; Khadka et al., 2012; Khadka et al., 2013; Lamoureux et al., 2009; McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009) or approve (Pesudovs et al., 2007; Khadka et al., 2013; Khadka et al., 2011; Wright and Stone, 1999; Garamendi et al., 2006; Gothwal et al., 2009c; Khadka et al., 2016; Marella et al., 2010; Pesudovs et al., 2010) a questionnaire based on the misfit statistics of data from a single and potentially non-representative cohort of patients, occasionally with a relatively small sample size (Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010; McAlinden et al., 2011; Huang et al., 2017; Khadka et al., 2011).

In this study, we state that a questionnaire is "Rasch valid" if the items and responses fit the Rasch model, and "Rasch invalid" if the items or responses show outliers and therefore do not fit the Rasch model.

In this section, we will present a case study to illustrate how the proposed approach enables the use of Rasch analysis as a decision support tool for postoperative patient follow-up, in order to improve the patient care experience.

### 2.4.2 The PRO instrument

The PRO instrument, used for this study, is a previously developed Quality of Vision (QoV) questionnaire (McAlinden et al., 2010), from which only the bothersome scale was used to reduce number of questions. The questionnaire attained information on the presence of various dysphotopsias and visual disturbances that a patient may experience, and the annoyance of each side effect to the patient. Patients reported the degree of annoyance of the nine vision related symptoms presented in Table 5. The choice of these nine symptoms was motivated by their substantive representativeness of QoV. This QoV questionnaire uses pictures to further aid understanding of the dysphotopsias or visual disturbances being questioned. A sample of the pictures used is provided in Appendix C. In addition to the original questionnaire a linear 0-10 scale was incorporated to define each patient's own subjective view of their overall QoV, in order to gain a better understanding of postoperative satisfaction.

**Remark 2:** In contrast with conditions in Remark 1 for the assessment of the LogMAR chart for visual acuity test, for ophthalmic PRO questionnaires in general and the QoV questionnaire in particular, the context is as follows.

1. the responses, to the questions associated to the symptoms listed in the QoV questionnaire, are subjective, as they reflected the feeling of the patient regarding these symptoms;

2. the symptoms, listed in the QoV questionnaire, are not ordered at all, since they are assumed to be totally independent; therefore, there is no specific response pattern expected according to patients' and symptoms' locations; for instance, a patient with a given location value is not expected to be affected by a symptom with a lower location; therefore, the outfit and infit statistics need to be interpreted differently in this context, as described in section 2.4.4;

3. the scenario does not fully comply with some of the key assumptions behind the Rasch model, in particular Assumptions 3 and 4; therefore, the latent trait of interest may not be unidimensional.

### 2.4.3 Participants

The participants consist of a cohort of 481 patients who had implantation of a Lentis Mplus LS-312 MF30 (Oculentis, GmbH) multifocal IOLs from Cathedral Eye Clinic, Belfast. Patients were thoroughly assessed and informed of the risks of the procedure and all patients gave their informed consent for their anonymised data to be submitted for audit and publication. The patients received multifocal IOLs following either refractive lens exchange (RLE) or cataract extraction surgery. Full ophthalmologic examination was performed on each patient approximately one month and one year postoperatively following the implantation of the IOLs. In each case the QoV questionnaire was completed with an optometrist to ensure understanding of the questions. The summary statistics of the patients are presented in Table 6. Among these 481 patients, 125 and 160 declared not suffering at all from any of the nine symptoms one month and one year postoperatively, respectively. Therefore, these patients have been discarded from the analysis so that the JMLE method operates properly.

### 2.4.4 Contextualisation of the Rasch model

In order to properly interpret the outputs of the Rasch model we need to establish the meaning of the terminologies used in Rasch analysis within the context of the ophthalmic questionnaire of interest. In this context,

(i) the ability parameter $\hat{a}_p$, associated to an examinee *p* in the Rasch model, corresponds to the location (in logit), in terms of perception of visual discomfort, for the patient *p*; the lower the value of this parameter the lower the perception of visual discomfort, whereas the higher the value of the parameter the higher the perception of visual discomfort.

(ii) the difficulty parameter $\hat{d}_i$, associated to an item *i* in the Rasch model, corresponds to the location (in logit), in terms of "non-prevalence" within the cohort, for the symptom *i*; the lower the value of this parameter the higher the proportion of patients within the cohort affected by the symptom, whereas the higher the value of the parameter the lower the proportion of patients affected by the symptom.

(iii) the probability for a patient *p* to give a response category $\eta$ to the question associated with symptoms *i*, given her / his location, in terms of his / her perception of visual discomfort, $\hat{a}_p$, and the location of the symptom, in terms of its prevalence within the cohort, $\hat{d}_i$, is as follows:

$$P(u_{pi} = \eta | \hat{a}_p, \hat{d}_i, \hat{h}_t) = \frac{e^{\sum_{t=0}^{\eta}(\hat{a}_p - \hat{d}_i + \hat{h}_t)}}{\sum_{\eta=0}^{k} e^{\sum_{t=0}^{\eta}(\hat{a}_p - \hat{d}_i + \hat{h}_t)}}, \tag{5}$$

where the parameter *t* denotes the common threshold associated with all the items for the category response *t*.

The calibration step of Rasch analysis enables the researcher at a glance to compare and contrast different populations and define whether the examined items hold the same weight or relevance within the particular cohort. An example might be how car drivers are affected by glare compared to non-drivers. Different positioning of the items might at a glance highlight the differential importance of glare in these two different populations of patients. The fit analysis however would help to quickly highlight individuals potentially with ocular problems including higher levels of astigmatism or macular problems such as cystoid macular oedema (CMO) or age-related macular degeneration (AMD), which might produce values of the misfit statistics deviating significantly from the expected values for the Rasch model.

## 2.5 Results

The types of different response categories for the questions, described in Table 5, suggest a polytomous Rasch model as the most appropriate option. The RSM (Andrich, 1978) was used to analyse the questionnaire data, and the parameters of the model were estimated by mean of the JMLE method, implemented using the Matlab® software (MATLAB. Version 8.4.0.150421 (R2014b). The MathWorks Inc. Natick, Massachusetts; 2014).

The objective of the analysis was not to select only symptoms which fit the Rasch model but to ensure that most of the symptoms affecting the QoV, in general, are covered. Furthermore, the interpretation of the outputs of the model is specific to the data of the response matrix under investigation.

### 2.5.1 Analysis of the questionnaire data collected one month postoperatively

From the estimates of symptom locations in Table 7 and depicted in Figure 4, the most prevalent symptom within the cohort was Starbursts (ST), followed by Glare (GL), Blurred vision (BV), Haloes and Fluctuation (HL, FL), Hazy vision (HV) and Double images (DI), respectively; whereas the cohort under investigation was barely affected by Difficulty in depth perception (DDP) and Distortion (DS). These results are corroborated by the Item Characteristics Curves (ICCs) depicted in Figure 5, where the ICC for the response category "Not at all" dominates nearly all the ICCs for the other response categories for Distortion, and the ICCs of the response categories "Not at all" and "A little" dominate all the ICCs for the other response categories for Difficulty in depth perception. Furthermore, the ICCs suggest that the response category "Quite" is the least reported by this cohort of patients. The relatively high Outfit and / or Infit MNSQ values, compared to 1, for Group 2, Group 10, Group 16 and 17 indicated that most of the patients in these groups were annoyed by both the most and the least prevalent symptoms but not some of the other symptoms. However, this did not make these patients outliers.

The patients from this cohort who experienced most discomfort with their vision, and thus, require additional care and monitoring, were those with higher location estimates. The top 10 patients, within the cohort, who experienced most discomfort with their vision are those in the rows highlighted in grey in Table 8, i.e. from Groups 12 to 17. From the questionnaire responses for these patients presented in Table 9, most of them reported significant discomfort from Glare (GL), Haloes (HL) and Starbursts (ST) but less from Distortion (DS) and Double images (DI) and to a certain extent Difficulty in depth perception (DDP). However, for the other symptoms their perception of visual discomfort is quite mixed.

### 2.5.2 Analysis of the questionnaire data collected one year postoperatively

From the estimates of the symptom locations in Table 10 and depicted in Figure 6, the most prevalent symptom, within the cohort, was Glare (GL), followed by Starbursts (ST), Fluctuation (FL), Haloes (HL), Blurred vision (BV), Hazy vision

(HV), Double images (DI) and Difficulty in depth perception (DDP), respectively; whereas the cohort under investigation was barely affected by Distortion (DS). These results are confirmed by the ICCs depicted in Figure 7, where the ICC for the response category "Not at all" dominates nearly all the ICCs for the other response categories for Distortion. Moreover, the ICCs suggest that the response category "Quite" was barely reported by the patients this time round. However, this does not provide enough ground to dismiss this response category. Only a continuous analysis of data collected from various cohorts of patients might enable the confirmation of an excessive subscaling of the response options, if any. The relatively high Infit MNSQ values, compared to 1, for the symptom "Distortion", indicated that this symptom affected patients who were the most and least annoyed with their vision, but this did not make this symptom irrelevant. The relatively high Outfit and / or Infit MNSQ values, compared to 1, for Group 4, Group 9, Group 11, Group 12, Group 15 and 16 indicated that most of the patients in these groups were most annoyed by both the most and the least prevalent symptoms but not some of the symptoms in between (Table 11). However, this did not make these patients outliers.

One year postoperatively, the top 10 patients who were most annoyed with their vision are those in rows highlighted in grey in Table 11, i.e. from Groups 15 to 18. From the questionnaire responses, presented in Table 12, most of them reported significant discomfort from Glare (GL), Haloes (HL), Starbursts (ST), Blurred vision (BV), Hazy vision (HV) but not from Distortion (DS). Their perception of visual discomfort from the other symptoms is mixed.

### 2.5.3 Comparative analysis of the questionnaire data collected one month and one year postoperatively

The distribution of the locations of symptoms (in logit), depicted in Figure 8, showed a noticeable decrease in the prevalence of the symptom Distortion (DS) and a slight decrease in the prevalence of the symptoms Difficulty in depth perception (DDP) and Blurred vision (BV) one year postoperatively, while an increase in the prevalence of the symptoms Glare (GL), Fluctuation (FL) and Haloes (HL) are observed within the overall cohort of patients.

The distribution of the locations of patients (in logit), in Figure 9 (a), showed globally little variation in terms of the level of perception of visual discomfort within the cohort one month and one year postoperatively. However, the results indicate that Patient 263 (Group 18) was significantly annoyed with his / her vision, one year postoperatively which was not the case one month postoperatively. From the distribution of patients per group, in Figure 9 (b), there was a relative increase in both the fractions of patients who experienced less and more visual discomfort one year postoperatively compared to eleven months earlier. The cohort of the top 10 patients, who were most annoyed with their vision one month postoperatively (Table 9) is entirely different from the cohort of the top 10 who experienced most discomfort one year postoperatively (Table 12). The top 10 patients, who were most annoyed with their vision one month postoperatively, highlighted in blue and bold in Table 11, have shown a significant improvement in their perception of visual discomfort. On the other hand, the top 10 patients who were most annoyed with their vision one year postoperatively, highlighted in red and bold in Table 8, were generally mildly annoyed with their vision one month postoperatively. The location distribution results, depicted in Figure 10, showed that the level of perception of visual discomfort from the top 10 patients is substantially higher one year postoperatively compared to one month postoperatively.

## 2.6 Discussion

Following the approach advocated in previous studies (Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010) which use the misfit statistics of the items and the ICCs, to dismiss (Pesudovs et al., 2007; Finger et al., 2012; Gothwal et al., 2009a; Gothwal et al., 2010; Khadka et al., 2012; Khadka et al., 2013; Lamoureux et al., 2009; McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009) or approve (Pesudovs et al., 2007; Khadka et al., 2013; Khadka et al., 2011; Wright and Stone, 1999; Garamendi et al., 2006; Gothwal et al., 2009c; Khadka et al., 2016; Marella et al., 2010; Pesudovs et al., 2010) an ophthalmic questionnaire, the following conclusions can be drawn on the QoV questionnaire used in this study: one month postoperatively, the values of the Outfit MNSQ and Infit MNSQ statistics, for all the symptoms, were below the 1.5 threshold and were not far away from the expected value of 1; all the response categories were expressed in the ICCs of most of the symptoms, except for Double Images (DI), Distortion (DS) and Difficulty in depth perception (DDP); hence, the QoV questionnaire is “Rasch-valid” after the removal of the aforementioned three symptoms.

On the other hand, the same questionnaire, administered to the same cohort of patients, becomes “Rasch-invalid" eleven months later, i.e. one year postoperatively, since the category response "Quite" was no longer expressed in the ICCs of all the symptoms and the values of the Infit MNSQ statistics for the symptoms Double images (DI) and Distortion (DS) exceeded the 1.5 threshold.

These findings shed light on some of the major flaws associated with the current most advocated approach for validating ophthalmic questionnaires using Rasch analysis (Finger et al., 2012; Gothwal et al., 2009b; Gothwal et al., 2010), which cast some serious doubt about its “validity”. Unlike the current applications of the Rasch model to validate ophthalmic questionnaires, the alternative application of Rasch analysis, proposed in this study, enables a meaningful use of Rasch analysis as an intelligent decision support system for deriving valuable insights from data collected via ophthalmic questionnaires. At the population level, such an approach enables one to investigate the prevalence of ophthalmic symptoms across different cohorts of patients, through a better characterisation of patient groups preoperatively and an appropriate follow-up postoperatively, in order to assess the effectiveness of a treatment, such as different types of IOLs or different surgical procedures. At the individual level, the new approach can be applied across a population at different time points and identify patients who experienced most visual discomfort preoperatively and / or postoperatively, so that additional appropriate care and monitoring can be dedicated to them. This new perspective will pave the way for a more adequate application of Rasch analysis within the context of ophthalmic questionnaires, so that insights gained from the analysis can be exploited to enhance the quality of care and patient care experience.

For illustrative purposes, the new approach was used to investigate the prevalence of QoV related symptoms across a cohort of patients at different time points. The analysis of the questionnaire data, using the new stratified approach in the application of Rasch model, was used to characterise the variation in the prevalence of symptoms, from one month to one year postoperatively, and to identify the patients who experience the most visual discomfort at these two time points, and therefore can receive additional care and monitoring. The purpose of this paper was not to attempt to advocate a new validation method of ophthalmic questionnaires or to supersede Rasch analysis but to highlight the shortcomings of Rasch analysis in dismissing and approving questionnaires, and outlining Rasch analysis as a decision support tool for deriving insights from data obtained using ophthalmic questionnaires. We will use the alternative application of Rasch analysis to assess and compare the effectiveness of various IOLs, and to investigate the impact of patient characteristics such as lifestyle, age and gender, on the perception of visual discomfort postoperatively. Our future work will also further investigate validation methods of ophthalmic questionnaires.

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**2.8 FIGURES & TABLES**

**Figure 1 -** Examinee-item map along the line characterising the underlying continuum latent trait.

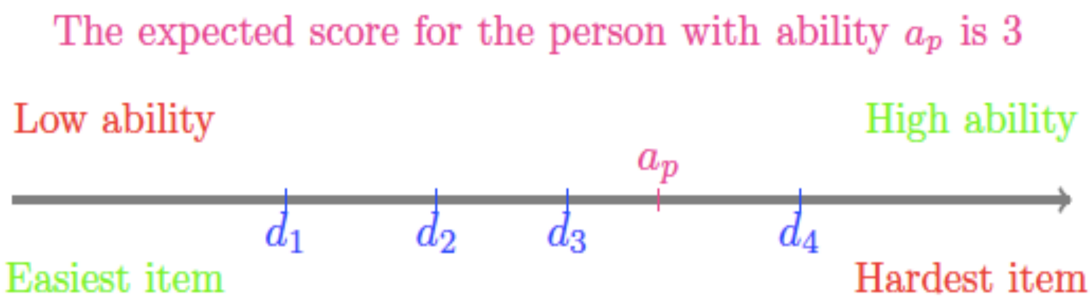


**Figure 2** - A LogMAR chart for visual acuity testing, with 9 items.

**Figure 3 -** Patient-item map along the line characterising their locations (in logit), in terms of visual acuity and difficulty to read, respectively.

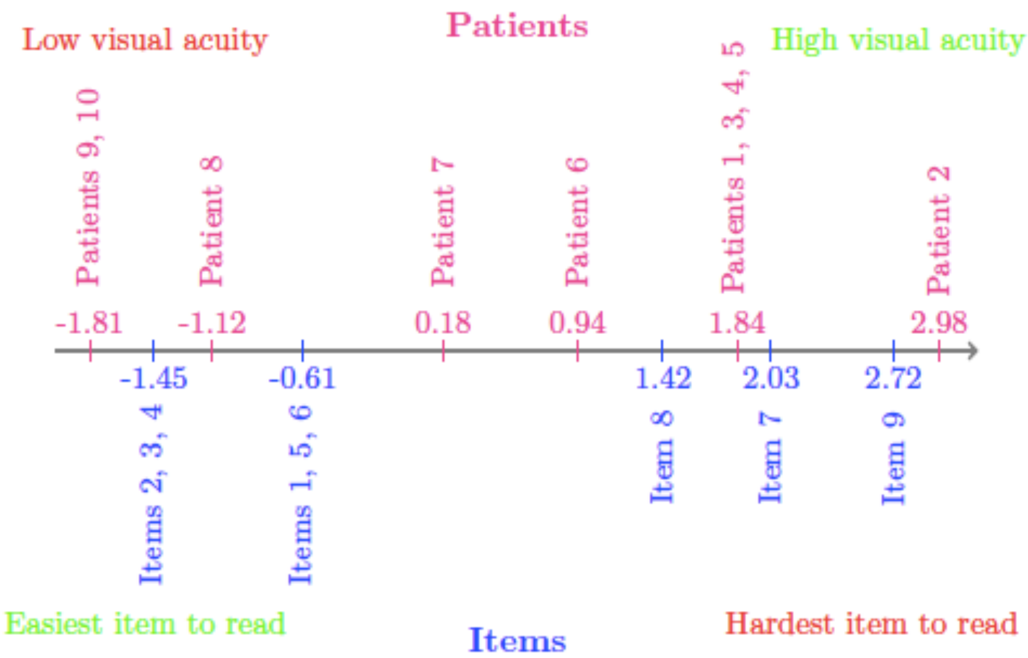


**Figure 4** - Patient-symptom map for questionnaire data collected one month postoperatively.

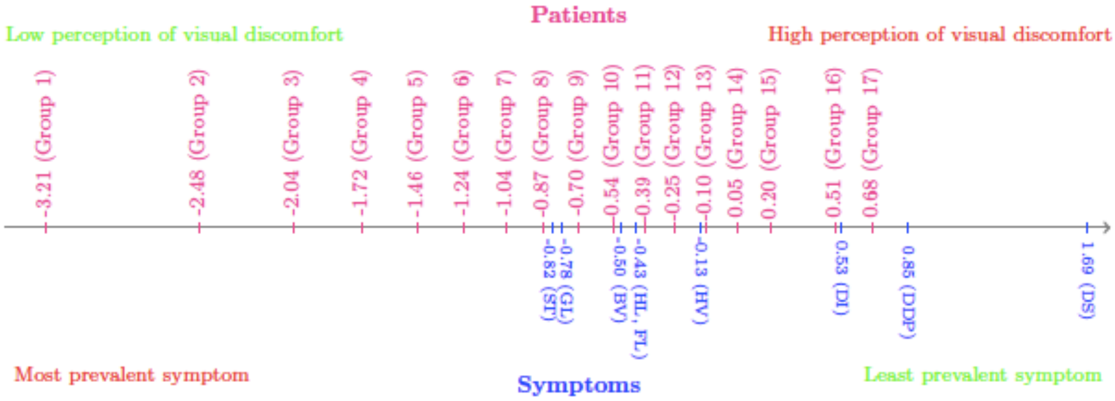
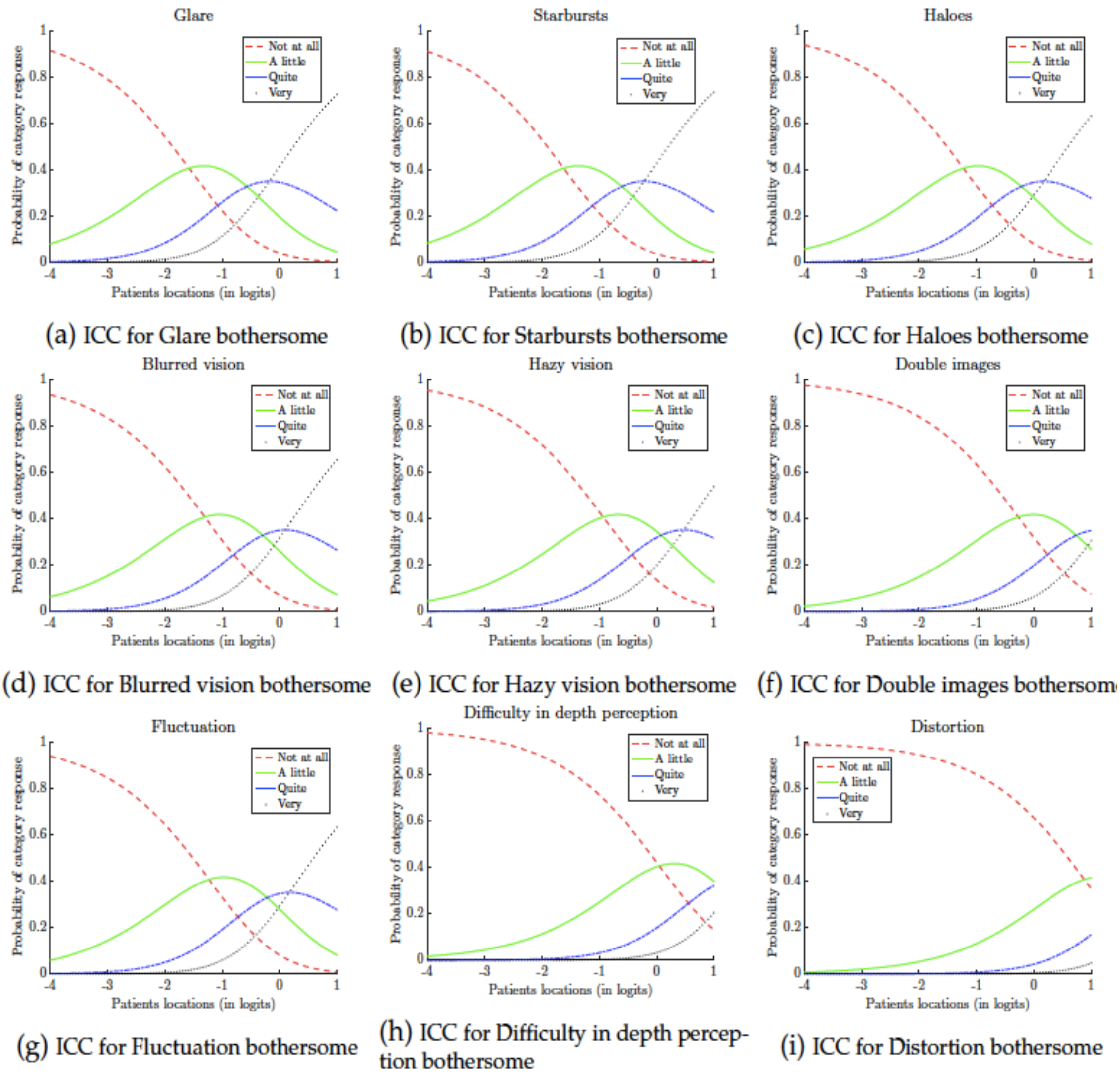


**Figure 5** - Item Characteristics Curves (ICC) for the questionnaire data collected one month postoperatively.




(a) ICC for Glare bothersome
(b) ICC for Starbursts bothersome
(c) ICC for Haloes bothersome
(d) ICC for Blurred vision bothersome
(e) ICC for Hazy vision bothersome
(f) ICC for Double images bothersom
(g) ICC for Fluctuation bothersome
(h) ICC for Difficulty in depth perception bothersome
(i) ICC for Distortion bothersome

**Figure 6** - Patient-symptom map from QoV questionnaire data collected one year postoperatively.

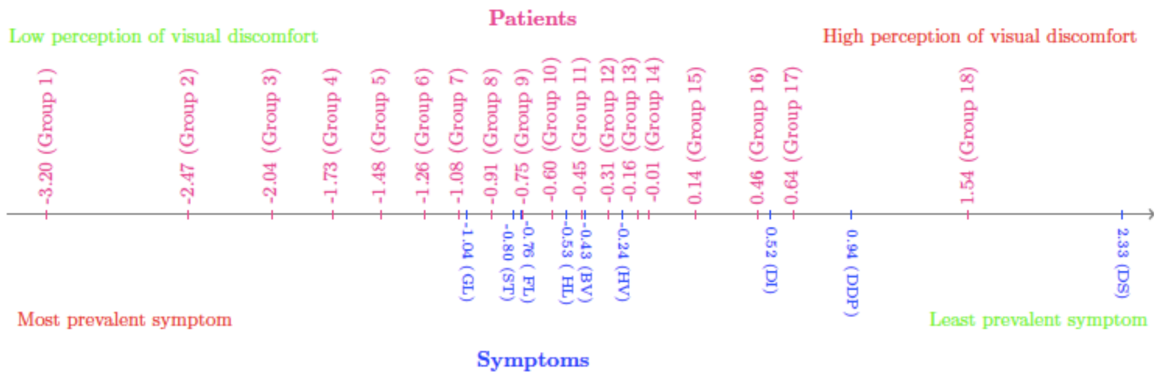
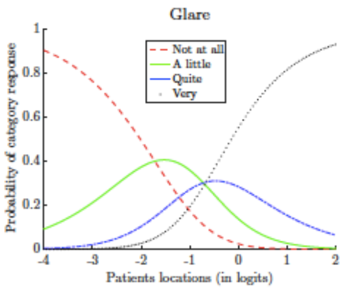
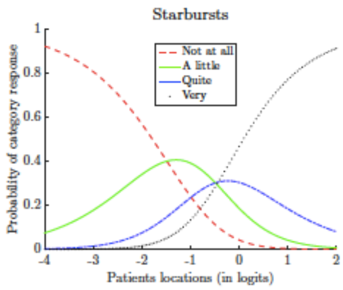


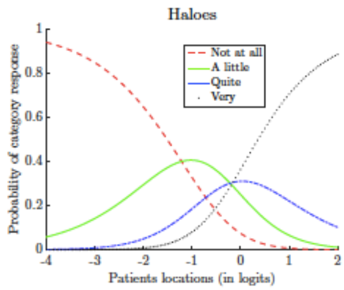
**Figure 7** - Item Characteristics Curves (ICC) for the questionnaire data collected one year postoperatively.



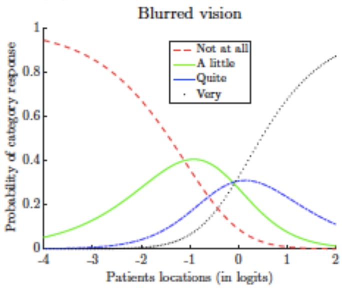

(a) ICC for Glare bothersome



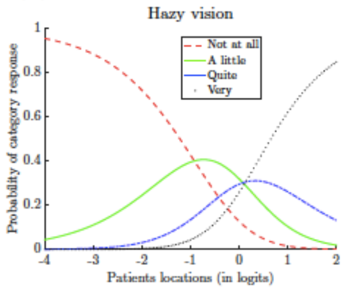

(b) ICC for Starbursts bothersome



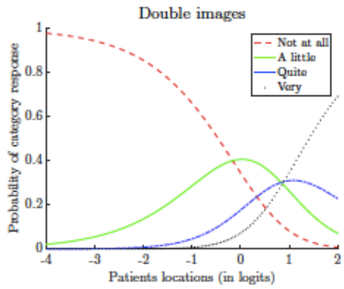

(c) ICC for Haloes bothersome



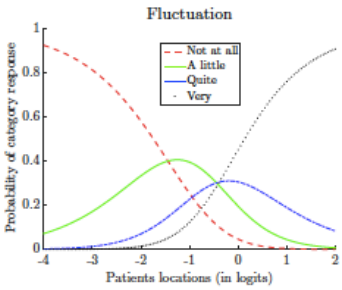

(d) ICC for Blurred vision bothersome



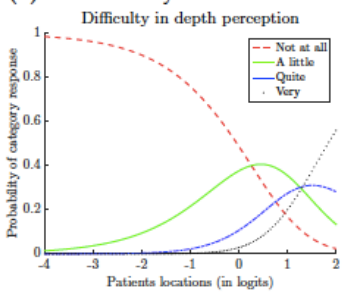

(e) ICC for Hazy vision bothersome



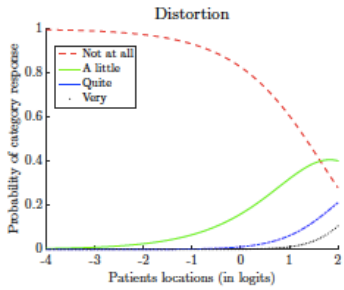

(f) ICC for Double images bothersome




(g) ICC for Fluctuation bothersome




(h) ICC for Difficulty in depth perception bothersome




(i) ICC for Distortion bothersome

**Figure 8** - Location distributions of symptoms one month and one year postoperatively.

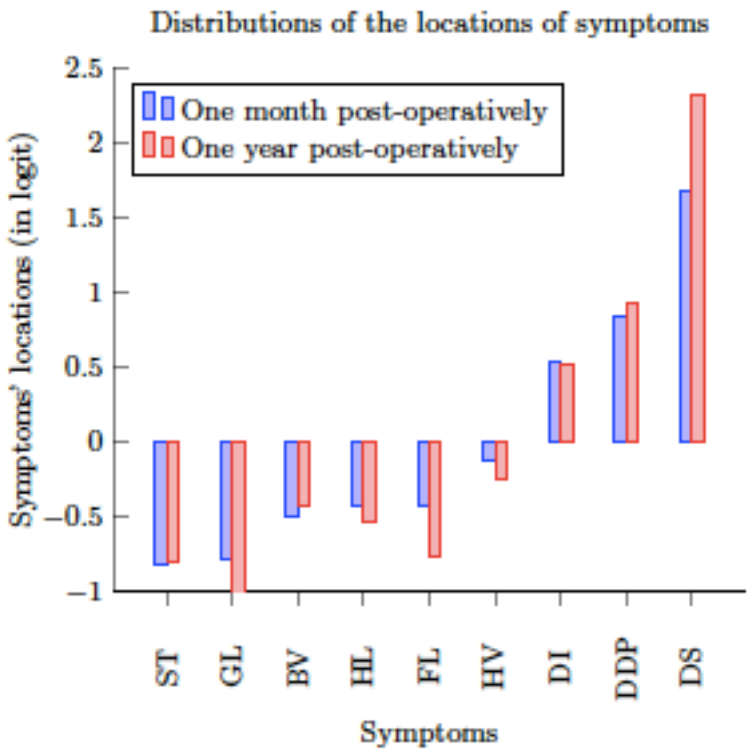
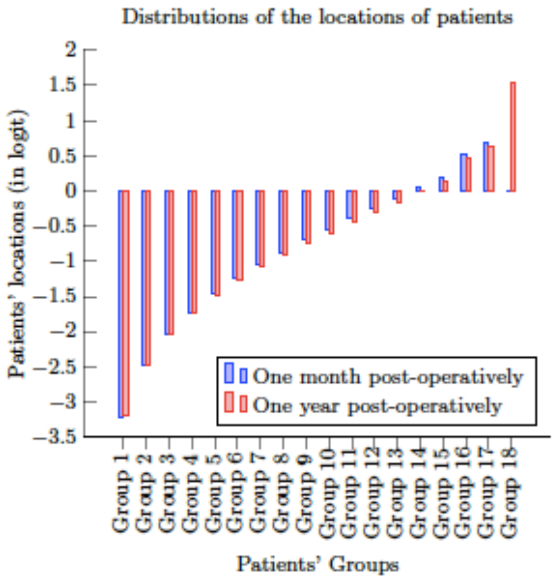
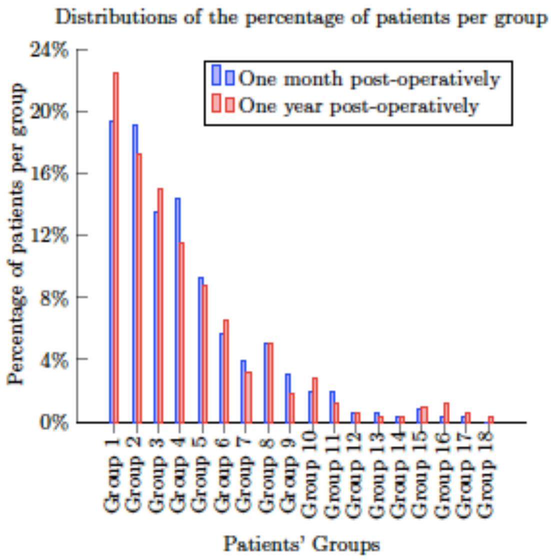


**Figure 9** - (a) Location distributions of patients one month and one year postoperatively; (b) Distributions of patient percentage per group one month and one year postoperatively.




(a)




(b)

**Figure 10** - Location distributions of the top 10 patients, who were most annoyed with their vision, one month and one year postoperatively.

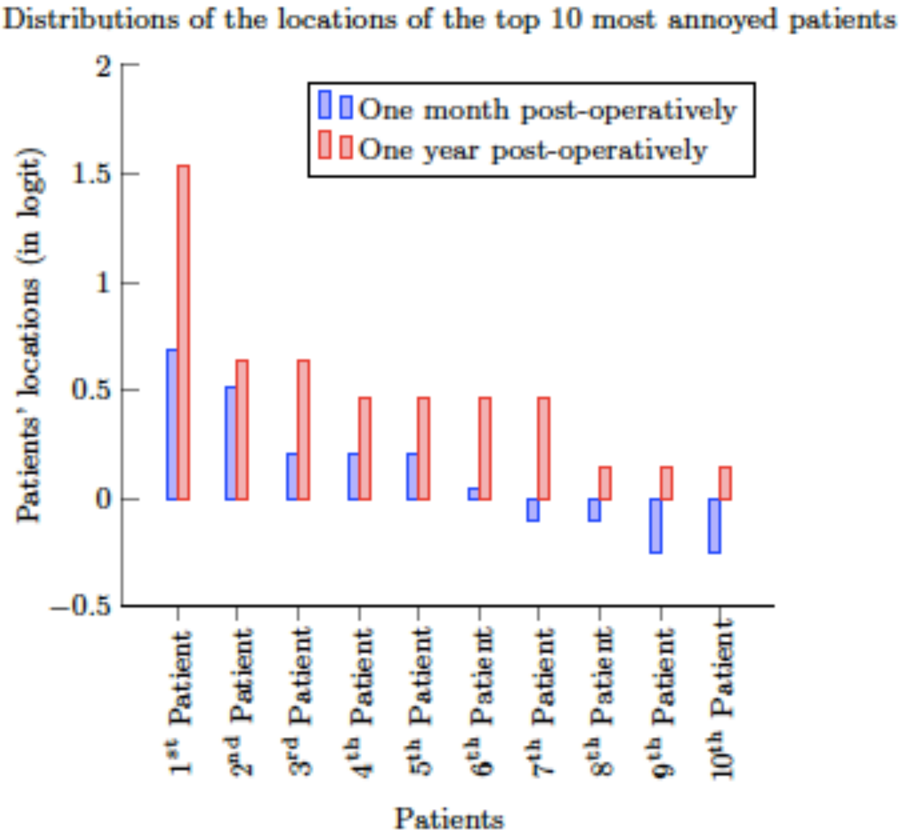


**Table 1** - General form of the data matrix for the Rasch model.

$$
\begin{array}{cc|cccccc|}
 & & & & \text{Items} & & & \\
 & & 1 & 2 & \cdots & i & \cdots & n \\
\cline{3-8}
\multirow{6}{*}{\rotatebox{90}{Examinees}} & 1 & u_{11} & u_{12} & \cdots & u_{1i} & \cdots & u_{1n} \\
 & 2 & u_{21} & u_{22} & \cdots & u_{2i} & \cdots & u_{2n} \\
 & \vdots & \vdots & \vdots & \vdots & \vdots & \vdots & \vdots \\
 & p & u_{p1} & u_{p2} & \cdots & u_{pi} & \cdots & u_{pn} \\
 & \vdots & \vdots & \vdots & \vdots & \vdots & \vdots & \vdots \\
 & m & u_{m1} & u_{m2} & \cdots & u_{mi} & \cdots & u_{mn} \\
\cline{3-8}
\end{array}
$$

**Table 2** - The dichotomous response data matrix from a visual acuity test using the LogMAR chart in Figure 2, and the corresponding location estimates for patients and items.

| Items / Patients | Item 1 | Item 2 | Item 3 | Item 4 | Item 5 | Item 6 | Item 7 | Item 8 | Item 9 | $r_p$ | $\mu_p$ | $\hat{a}_p^0$ | $\hat{a}_p^*$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Patient 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 7 | 0.78 | 1.25 | 1.84 |
| Patient 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 8 | 0.89 | 2.08 | 2.98 |
| Patient 3 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 7 | 0.78 | 1.25 | 1.84 |
| Patient 4 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 7 | 0.78 | 1.25 | 1.84 |
| Patient 5 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 7 | 0.78 | 1.25 | 1.84 |
| Patient 6 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 6 | 0.67 | 0.69 | 0.94 |
| Patient 7 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 5 | 0.56 | 0.22 | 0.18 |
| Patient 8 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 3 | 0.33 | -0.69 | -1.12 |
| Patient 9 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 2 | 0.22 | -1.25 | -1.81 |
| Patient 10 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 2 | 0.22 | -1.25 | -1.81 |
| $r_i$ | 7 | 8 | 8 | 8 | 7 | 7 | 3 | 4 | 2 | | | | |
| $\mu_i$ | 0.7 | 0.8 | 0.8 | 0.8 | 0.7 | 0.7 | 0.3 | 0.4 | 0.2 | | | | |
| $\hat{d}_i^0$ | -0.85 | -1.39 | -1.39 | -1.39 | -0.85 | -0.85 | 0.85 | 0.41 | 1.39 | | | | |
| $\hat{d}_i^{0(\mathrm{Adj})}$ | -0.39 | -0.93 | -0.93 | -0.93 | -0.39 | -0.39 | 1.30 | 0.86 | 1.83 | | | | |
| $\hat{d}_i^*$ | -0.61 | -1.45 | -1.45 | -1.45 | -0.61 | -0.61 | 2.03 | 1.42 | 2.72 | | | | |

**Table 3** - Estimates of item location (in logits), in terms of difficulty to read, and the corresponding Standard Error, Mean square (MNSQ) Infits and Outfits. The fit statistics, highlighted in red, are those exceeding the threshold of 1.5.

| Item ID | Item location (in logit) | Standard Error | Outfits MNSQ | Infits MNSQ |
|---|---|---|---|---|
| Item 1 | -0.61 | 0.89 | 1.47 | 1.18 |
| Item 2 | -1.45 | 0.96 | 0.4 | 0.82 |
| Item 3 | -1.45 | 0.96 | 0.26 | 0.51 |
| Item 4 | -1.45 | 0.96 | 0.4 | 0.82 |
| Item 5 | -0.61 | 0.89 | 0.51 | 0.81 |
| Item 6 | -0.61 | 0.89 | 0.97 | 1.25 |
| Item 7 | 2.03 | 0.80 | 0.73 | 1.00 |
| Item 8 | 1.42 | 0.78 | 0.85 | 0.92 |
| Item 9 | 2.72 | 0.87 | 9.46 | 1.18 |

**Table 4** - Estimates of patient location (in Logit), in terms of visual acuity, and the corresponding standard error, mean square (MNSQ) Infits and Outfits. The fit statistics, highlighted in red, are those exceeding the threshold of 1.5.

| Patient ID | Patient location (in logit) | Standard Error | Outfits MNSQ | Infits MNSQ |
|---|---|---|---|---|
| Patient 1 | 1.84 | 0.99 | 1.56 | 1.38 |
| Patient 2 | 2.98 | 1.19 | 0.67 | 1.36 |
| Patient 3 | 1.84 | 0.99 | 0.25 | 0.46 |
| Patient 4 | 1.84 | 0.99 | 0.25 | 0.46 |
| Patient 5 | 1.84 | 0.99 | 0.25 | 0.46 |
| Patient 6 | 0.94 | 0.91 | 1.02 | 1.23 |
| Patient 7 | 0.18 | 0.84 | 0.47 | 0.58 |
| Patient 8 | -1.12 | 0.80 | 0.84 | 1.14 |
| Patient 9 | -1.81 | 0.87 | 0.50 | 0.77 |
| Patient 10 | -1.81 | 0.87 | 10.89 | 1.65 |

**Table 5** - QoV questionnaire: symptoms, questions and response options.

| Symptom label | Symptom denomination | Questions | Response Options |
|---|---|---|---|
| GL | Glare | How bothersome is the glare? | Not at all, A little, Quite, Very |
| HL | Haloes | How bothersome are the haloes? | Not at all, A little, Quite, Very |
| ST | Starburst | How bothersome are the starbursts? | Not at all, A little, Quite, Very |
| HV | Hazy vision | How bothersome is the hazy vision? | Not at all, A little, Quite, Very |
| BV | Blurred vision | How bothersome is the blurred vision? | Not at all, A little, Quite, Very |
| DS | Distortion | How bothersome is the distortion? | Not at all, A little, Quite, Very |
| DI | Double image | How bothersome are the double images? | Not at all, A little, Quite, Very |
| FL | Fluctuation | How bothersome is the fluctuation in your vision? | Not at all, A little, Quite, Very |
| DDP | Difficulty in depth perception | How bothersome is the difficulty in depth perception? | Not at all, A little, Quite, Very |

**Table 6** - Participant demographics

| Characteristics | Result |
|---|---|
| Mean age (in years) ± SD | 62 ±9.00 |
| Age range (in years) | 30-93 |
| Sex, Number (%) | |
| Male | 195 (40.5%) |
| Female | 286 (59.5%) |

**Table 7 -** Symptom location estimates (in logit), in terms of their level of prevalence within the cohort, and the corresponding standard errors, infits MNSQ and outfits MNSQ values, obtained from QoV questionnaire data collected one month postoperatively.

| Symptom label | Symptom denomination | Symptom location (in logit) | Standard Error | Outfit MNSQ | Infit MNSQ |
|---|---|---|---|---|---|
| ST | Starbursts | -0.82 | 0.07 | 0.92 | 0.93 |
| GL | Glare | -0.78 | 0.07 | 0.85 | 0.86 |
| BV | Blurred vision | -0.50 | 0.08 | 0.97 | 0.99 |
| HL, FL | Haloes, Fluctuation | -0.43 | 0.08 | 0.94 | 0.91 |
| HV | Hazy vision | -0.13 | 0.09 | 0.84 | 0.97 |
| DI | Double images | 0.53 | 0.11 | 1.25 | 1.42 |
| DDP | Difficulty in depth perception | 0.85 | 0.13 | 1.19 | 1.38 |
| DS | Distortion | 1.69 | 0.19 | 1.05 | 1.45 |

**Table 8** - Patient location estimates (in logit), in terms of their perception of visual discomfort, and the corresponding standard errors, infit MNSQ and outfit MNSQ values, obtained from QoV questionnaire data collected one month postoperatively. The patient IDs, highlighted in red, correspond to the top 10 patients with the most visual discomfort, one year postoperatively.

| Group ID | Patients ID | Patient location (in logit) | Standard Error | Outfit MNSQ | Infit MNSQ | Percentage of patients per group |
|---|---|---|---|---|---|---|
| Group 1 | 1, 2, 3, 4, 19, 21, 28, 29, 33, 52, 56, 60, 65, 68, 69, 70, 76, 85, 91, 110, 114, 118, 122, 125, 132, 137, 142, 144, 150, 161, 164, 174, 175, 176, 179, 181, 182, 186, 188, 198, 199, 207, 214, 218, 231, 233, 236, 238, 242, 243, 252, 258, 267, 271, 276, 284, 285, 288, 297, 309, 313, 318, 322, 327, 336, 340, 351, 352, 354 | -3.21 | 1.02 | 0.50 | 0.80 | 19.38% |
| Group 2 | 5, 15, 18, 31, 34, 35, 39, 40, 42, 44, 57, 58, 66, 71, 72, 74, 80, 81, 83, 87, 99, 106, 108, 112, 113, 123, 131, 133, 134, 138, 152, 156, 158, 163, 168, 170, 171, 172, 187, 190, 195, 197, 205, 208, 237, 239, 241, 253, 255, 256, 274, 279, 283, 296, 302, 311, 312, 314, 315, 317, 324, 329, 331, 332, 335, 337, 346, 350 | -2.48 | 0.73 | 5.57 | 2.28 | 19.10% |
| Group 3 | 10, 11, 12, 16, 20, 23, 25, 36, 48, 54, 59, 64, 84, 100, 109, 115, 140, 143, 154, 160, 173, 180, 185, 189, 196, 202, 213, 219, 240, 246, 248, 250, 260, 261, 268, 277, 278, 280, 282, 295, 298, 310, 319, 320, 323, 338, 339, 348 | -2.04 | 0.61 | 0.64 | 0.76 | 13.48% |
| Group 4 | 17, 45, 47, 50, 55, 92, 93, 95, 98, 101, 102, 103, 105, 111, 116, 117, 135, 145, 146, 147, 149, 151, 165, 169, 184, 191, 192, 193, 210, 220, 224, 225, 230, 234, 245, 249, 257, 262, 265, 270, 275, 287, 290, 299, 306, 308, 321, 328, 334, 353, 355 | -1.72 | 0.53 | 0.43 | 0.50 | 14.33% |
| Group 5 | 8, 13, 14, 24, 26, 30, 37, 43, 46, 51, 78, 90, 97, 124, 129, 139, 183, 200, 201, 212, 226, 227, 244, 254, 272, 281, 291, 301, 325, 326, 343, 344, 356 | -1.46 | 0.49 | 0.25 | 0.24 | 9.27% |
| Group 6 | 38, 49, 73, 77, 82, 127, 159, 194, 209, 215, 217, 222, 232, 235, 247, 264, 304, 305, 330 | -1.24 | 0.45 | 0.74 | 0.83 | 5.62% |
| Group 7 | 6, 27, 41, 53, 89, 107, 136, 141, 177, 178, 221, 229, 251, 342 | -1.04 | 0.43 | 1.25 | 0.81 | 3.93% |
| Group 8 | 22, 61, 75, 79, 86, 119, 120, 148, 153, 162, 216, 263, 266, 289, 293, 303, 345, 349 | -0.87 | 0.41 | 0.72 | 0.29 | 5.06% |
| Group 9 | 32, 62, 63, 67, 128, 203, 204, 259, 273, 292, 333 | -0.70 | 0.40 | 1.10 | 1.05 | 3.09% |
| Group 10 | 126, 157, 167, 286, 300, 341, 347 | -0.54 | 0.39 | 2.49 | 1.48 | 1.97% |
| Group 11 | 96, 130, 155, 206, 211, 294, 307 | -0.39 | 0.39 | 1.34 | 1.51 | 1.97% |
| Group 12 | 88, 223 | -0.25 | 0.38 | 0.25 | 0.23 | 0.56% |
| Group 13 | 9, 94 | -0.10 | 0.38 | 0.88 | 0.83 | 0.56% |
| Group 14 | 269 | 0.05 | 0.39 | 1.12 | 1.14 | 0.28% |
| Group 15 | 104, 228, 316 | 0.20 | 0.39 | 1.53 | 1.64 | 0.84% |
| Group 16 | 166 | 0.51 | 0.40 | 2.24 | 1.98 | 0.28% |
| Group 17 | 121 | 0.68 | 0.42 | 1.78 | 2.09 | 0.28% |

**Table 9** - Questionnaire responses and locations (in logit) for the top 10 patients, who experienced most discomfort with their vision, identified by the Rasch model from QoV questionnaire data collected one month postoperatively.

| Patients order | Patients ID | GL | HL | ST | HV | BV | DS | DI | FL | DDP | Location (in logit) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1st Patient | 121 | Very | Very | Very | Not at all | Very | Not at all | Not at all | Very | Very | 0.68 |
| 2nd Patient | 166 | Very | Very | Not at all | Very | Very | Not at all | Not at all | Very | Quite | 0.51 |
| 3rd Patient | 316 | Very | Very | Very | Not at all | Very | Not at all | Not at all | Very | Not at All | 0.20 |
| 4th Patient | 228 | Very | Very | Very | Very | Quite | Not at all | Not at all | A little | Not at all | 0.20 |
| 5th Patient | 104 | Very | Very | Very | Very | Very | Not at all | Not at all | Not at all | Not at all | 0.20 |
| 6th Patient | 269 | Very | Not at all | Very | Quite | Quite | Not at all | Not at all | Quite | Quite | 0.05 |
| 7th Patient | 94 | Very | Quite | Very | Quite | Quite | Not at all | Not at all | A little | Not at all | -0.10 |
| 8th Patient | 9 | A little | Very | Very | A little | Quite | A little | Not at all | Quite | Not at all | -0.10 |
| 9th Patient | 88 | Quite | Quite | Quite | Quite | Quite | Not at all | A little | A little | Not at all | -0.25 |
| 10th Patient | 223 | Very | Quite | Quite | Not at all | Very | Not at all | Not at all | Quite | Not at all | -0.25 |

**Table 10** - Symptom location estimates (in logit), in terms of their level of prevalence within the cohort, and the corresponding standard errors, infits MNSQ and outfits MNSQ values, obtained from QoV questionnaire data collected one year postoperatively.

| Symptom label | Symptom denomination | Symptom location (in logit) | Standard Error | Outfit MNSQ | Infit MNSQ |
|---|---|---|---|---|---|
| GL | Glare | -1.04 | 0.07 | 0.80 | 0.80 |
| ST | Starbursts | -0.80 | 0.08 | 0.95 | 0.98 |
| FL | Fluctuation | -0.76 | 0.08 | 0.98 | 0.97 |
| HL | Haloes | -0.53 | 0.08 | 0.97 | 1.01 |
| BV | Blurred vision | -0.43 | 0.09 | 0.94 | 0.98 |
| HV | Hazy vision | -0.24 | 0.09 | 0.83 | 1.02 |
| DI | Double images | 0.52 | 0.12 | 1.30 | 1.57 |
| DDP | Difficulty in depth perception | 0.94 | 0.14 | 1.14 | 1.33 |
| DS | Distortion | 2.33 | 0.27 | 0.86 | 1.65 |

**Table 11** - Patient location estimates (in logit), in terms of their perception of visual discomfort, and the corresponding standard errors, infit MNSQ and outfit MNSQ values, obtained from QoV questionnaire data collected one year postoperatively. The patient IDs, highlighted in blue, correspond to the top 10 patients with the most visual discomfort, one month postoperatively.

| Group ID | Patients ID | Patient location (in logit) | Standard Error | Outfit MNSQ | Infit MNSQ | Percentage of patients per group |
|---|---|---|---|---|---|---|
| Group 1 | 1, 3, 10, 15, 16, 20, 22, 38, 48, 54, 57, 59, 61, 64, 65, 70, 77, 101, 103, 111, 116, 117, 124, 127, 128, 129, 130, 134, 135, 142, 146, 148, 150, 153, 158, 159, 166, 167, 171, 173, 181, 182, 188, 190, 192, 196, 201, 202, 207, 215, 222, 225, 227, 230, 234, 245, 247, 248, 249, 252, 253, 265, 276, 278, 280, 284, 287, 294, 304, 316, 318, 319 | -3.20 | 1.02 | 0.42 | 0.74 | 22.50% |
| Group 2 | 7, 19, 23, 30, 33, 35, 37, 40, 41, 47, 53, 55, 60, 62, 74, 88, 95, 97, 102, 118, 119, 123, 137, 141, 144, 145, 149, 161, 169, 175, 191, 218, 221, 226, 228, 241, 242, 244, 254, 256, 259, 273, 277, 282, 288, 289, 290, 296, 300, 301, 305, 306, 308, 311, 315 | -2.47 | 0.73 | 0.69 | 0.81 | 17.19% |
| Group 3 | 2, 12, 17, 34, 39, 42, 43, 45, 49, 52, 56, 67, 69, 80, 104, 107, 108, 138, 152, 157, 162, 163, 164, 168, 172, 174, 185, 186, 189, 199, 214, 217, 223, 232, 233, 243, 255, 257, 264, 266, 279, 285, 299, 302, 303, 310, 313, 314 | -2.04 | 0.60 | 0.54 | 0.62 | 15.00% |
| Group 4 | 4, 11, 14, 18, 21, 44, 76, 81, 84, 85, 87, 94, 96, 98, 120, 131, 132, 133, 136, 154, 170, 176, 177, 178, 193, 197, 206, 210, 213, 219, 237, 239, 246, 275, 292, 293, 317 | -1.73 | 0.53 | 2.34 | 1.50 | 11.56% |
| Group 5 | 5, 8, 13, 26, 50, 73, 79, 89, 91, 99, 109, 115, 155, 183, 184, 187, 209, 212, 220, 250, 251, 260, 267, 269, 286, 291, 307, 309 | -1.48 | 0.48 | 0.67 | 0.36 | 8.75% |
| Group 6 | 6, 9, 27, 28, 31, 32, 36, 66, 68, 71, 72, 100, 114, 156, 198, 203, 236, 240, 258, 271, 295 | -1.26 | 0.44 | 0.68 | 0.73 | 6.56% |
| Group 7 | 25, 75, 83, 112, 121, 160, 205, 224, 272, 320 | -1.08 | 0.42 | 0.91 | 1.16 | 3.13% |
| Group 8 | 29, 46, 51, 58, 78, 90, 105, 122, 125, 179, 200, 216, 235, 238, 270, 274 | -0.91 | 0.40 | 0.82 | 0.80 | 5.00% |
| Group 9 | 63, 82, 126, 165, 229, 261 | -0.75 | 0.39 | 1.45 | 1.81 | 1.88% |
| Group 10 | 92, 106, 140, 143, 147, 211, 268, 297, 312 | -0.60 | 0.39 | 0.63 | 0.66 | 2.81% |
| Group 11 | 110, 139, 231, 298 | -0.45 | 0.38 | 1.60 | 1.87 | 1.25% |
| Group 12 | 86, 195 | -0.31 | 0.38 | 2.76 | 2.47 | 0.63% |
| Group 13 | 93 | -0.16 | 0.38 | 0.98 | 1.13 | 0.31% |
| Group 14 | 283 | -0.01 | 0.39 | 0.41 | 0.39 | 0.31% |
| Group 15 | 113, 204, 281 | 0.14 | 0.39 | 2.12 | 2.37 | 0.94% |
| Group 16 | 24, 151, 180, 194 | 0.46 | 0.41 | 1.68 | 1.90 | 1.25% |
| Group 17 | 208, 262 | 0.64 | 0.43 | 0.81 | 1.03 | 0.63% |
| Group 18 | 263 | 1.54 | 0.54 | 1.05 | 0.88 | 0.31% |

**Table 12** - Questionnaire responses and locations (in logit) for the top 10 patients, who experienced most discomfort with their vision identified by the Rasch model from QoV questionnaire data collected one year postoperatively.

| Patients order | Patients ID | GL | HL | ST | HV | BV | DS | DI | FL | DDP | Location (in logit) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1st Patient | 263 | Very | Very | Very | Very | Quite | Quite | Quite | Quite | Quite | 1.54 |
| 2nd Patient | 262 | Very | Very | Very | Quite | Very | Not at all | Not at all | Very | A little | 0.64 |
| 3rd Patient | 208 | Very | Very | Very | Very | Very | Not at all | Not at all | Very | Not at all | 0.64 |
| 4th Patient | 194 | Very | A little | A little | Very | Very | Not at all | Very | Very | Not at all | 0.46 |
| 5th Patient | 180 | Very | Very | Very | Very | Very | Not at all | Not at all | Quite | Not at all | 0.46 |
| 6th Patient | 151 | Very | Very | Not at all | Very | Very | Not at all | Not at all | Very | Quite | 0.46 |
| 7th Patient | 24 | Very | Not at all | Very | Very | Very | Not at all | Very | Quite | Not at all | 0.46 |
| 8th Patient | 281 | Very | Very | Very | Not at all | Very | Not at all | Not at all | Very | Not at all | 0.14 |
| 9th Patient | 204 | Very | Very | A little | Quite | Not at all | Not at all | A little | Quite | Very | 0.14 |
| 10th Patient | 113 | Very | Very | Very | Not at all | Very | Not at all | Very | Not at all | Not at all | 0.14 |

## 2.9 APPENDICES

## APPENDIX A

### Derivation of the dichotomous Rasch model

If the responses to test items consist of only two categories then dichotomous item response models can be applied. Without loss of generality, we can assume that the response of any examinee *p* to any item *i*, $u_{pi}$, can only be either 0 or 1. From Assumption 3, the response of an examinee *p* to item *i*, $u_{pi}$, depends on a single parameter $\xi_{pi}$, which goes from 0 to ∞. Thus, the response probability for an examinee *p* to an item *i* can be defined by any continuous and monotonic function of $\xi_{pi}$, which takes on only the values from 0 to 1, as $\xi_{pi}$ goes from 0 to ∞. Rasch suggested (Rasch, 1980; Rasch, 1966) the following simple function:

$$f(\xi_{pi}) = \frac{\xi_{pi}}{1+\xi_{pi}}. \tag{6}$$

Therefore,

$$P(u_{pi}=1|\xi_{pi}) = \frac{\xi_{pi}}{1+\xi_{pi}}, \text{and} \tag{7}$$

$$P(u_{pi}=0|\xi_{pi}) = 1-\frac{\xi_{pi}}{1+\xi_{pi}} = \frac{1}{1+\xi_{pi}}. \tag{8}$$

Equations (7) and (8) can then be written in a general form, as follows

$$P(u_{pi}|\xi_{pi}) = \frac{(\xi_{pi})^{u_{pi}}}{1+\xi_{pi}}. \tag{9}$$

Substituting $\xi_{pi}$ by $a_p/d_i$ in equation (9) yields

$$P(u_{pi}|a_p,d_i) = \frac{\left(\frac{a_p}{d_i}\right)^{u_{pi}}}{1+\frac{a_p}{d_i}}. \tag{10}$$

However, the above formulation restricted the parameter $\xi_{pi}$ to vary from 0 to ∞. Since, $\xi_{pi} = a_p/d_i$, then this formulation restricted the ability and the difficulty parameters, $a_p$ and $d_i$, respectively, to be either both positive or negative. However, it would be preferable to have a formulation where both the ability and the difficulty parameters can be used irrespective of their signs. One way to address the limitation of the above formulation is to consider a logarithmic transformation of both the ability and difficulty parameters as follows:

$$\hat{a}_p = \log(a_p) \tag{11}$$
$$\hat{d}_i = \log(d_i). \tag{12}$$

Now, the rescaled ability and difficulty parameters $\hat{a}_p$ and $\hat{d}_i$, respectively vary from $-\infty$ to $+\infty$, and the following inverse transformation enables the recovery of the initial ability and difficulty parameters $a_p$ and $d_i$:

$$a_p = e^{\hat{a}_p} \tag{13}$$
$$d_i = e^{\hat{d}_i}. \tag{14}$$

Substituting $a_p$ and $d_i$ by $e^{\hat{a}p}$ and $e^{\hat{d}i}$ respectively, in equation (10) yields

$$P(u_{pi}|\hat{a}_p, \hat{d}_i) = \frac{\left(e^{\hat{a}_p} e^{-\hat{d}_i}\right)^{u_{pi}}}{1 + e^{\hat{a}_p} e^{-\hat{d}_i}} = \frac{e^{(\hat{a}_p - \hat{d}_i)u_{pi}}}{1 + e^{(\hat{a}_p - \hat{d}_i)}}. \tag{15}$$

Thus,

$$P(u_{pi} = 1|\hat{a}_p, \hat{d}_i) = \frac{e^{(\hat{a}_p - \hat{d}_i)}}{1 + e^{(\hat{a}_p - \hat{d}_i)}} = \frac{1}{1 + e^{-(\hat{a}_p - \hat{d}_i)}}, \text{and} \tag{16}$$
$$P(u_{pi} = 0|\hat{a}_p, \hat{d}_i) = \frac{1}{1 + e^{(\hat{a}_p - \hat{d}_i)}}. \tag{17}$$

## A.1 Some mathematical properties of the Rasch model

### A.1.1 Linearity.

The extension of the logarithmic transformation (11)-(12) to the parameter $\xi_{pi}$ leads to the following result:

$$\log(\xi_{pi}) = \log\left(\frac{a_p}{d_i}\right) = \log(a_p) - \log(d_i) = \log(e^{\hat{a}_p}) - \log(e^{\hat{d}_i}) = \hat{a}_p - \hat{d}_i. \qquad (18)$$

Hence, after the above logarithmic transformation, the response probability of an examinee *p* to an item *i* is governed by the difference between $\hat{a}_p$ and $\hat{d}_i$. In other words, the response probability depends only on the distance between the examinee's ability and the item difficulty parameters both on the logit scale, i.e. a line similar to the one described in Figure 1. Therefore, the derived model becomes an additive model.

### A.1.2 Separation of parameters.

Assumption 3 and Assumption 4 confer the Rasch model some desirable mathematical features, which enable the estimation of the two classes of parameters of the model, i.e. $\hat{a}_p$ and $\hat{d}_i$, from the data response matrix, independently from one another. Given the Rasch model (15) and its parameters $\hat{a}_p$ and $\hat{d}_i$, which are not known yet, and a response data matrix *U*, the probability of the whole response data matrix - i.e. the likelihood, denoted *L* - consists of the following continued product.

$$
\begin{aligned}
L = P(u_{pi}|\hat{a}_p, \hat{d}_i) = \prod_{p=1}^{m}\prod_{i=1}^{n}\frac{e^{(\hat{a}_p-\hat{d}_i)u_{pi}}}{1+e^{(\hat{a}_p-\hat{d}_i)}} \\
= \frac{\prod_{p=1}^{m}\prod_{i=1}^{n} e^{(\hat{a}_p-\hat{d}_i)u_{pi}}}{\prod_{p=1}^{m}\prod_{i=1}^{n}\left(1+e^{(\hat{a}_p-\hat{d}_i)}\right)} \\
= \frac{e^{\sum_{p=1}^{m}\sum_{i=1}^{n}(\hat{a}_p-\hat{d}_i)u_{pi}}}{\prod_{p=1}^{m}\prod_{i=1}^{n}\left(1+e^{(\hat{a}_p-\hat{d}_i)}\right)} \\
= \frac{e^{\sum_{p=1}^{m}\hat{a}_p\sum_{i=1}^{n}u_{pi}} \times e^{-\sum_{i=1}^{n}\hat{d}_i\sum_{p=1}^{m}u_{pi}}}{\prod_{p=1}^{m}\prod_{i=1}^{n}\left(1+e^{(\hat{a}_p-\hat{d}_i)}\right)}.
\end{aligned}
\tag{19}
$$

The most desirable parameters $\hat{a}_p$ and $\hat{d}_i$ for the Rasch model are those such that the likelihood, $L$, is maximal. However, obtaining these parameters from (19) can be tedious due to the complexity of the expression of likelihood $L$. On the other hand, the parameter $\hat{a}_p$ and $\hat{d}_i$, which maximise $L$ are identical to those which maximise the logarithm of $L$. The logarithm of $L$, i.e. the log likelihood, of the data matrix $U$, writes

$$
\Gamma = \log L = \sum_{p=1}^{m}\hat{a}_p s_p - \sum_{i=1}^{n}\hat{d}_i s_i - \sum_{p=1}^{m}\sum_{i=1}^{n}\log\left(1+e^{(\hat{a}_p-\hat{d}_i)}\right), \tag{20}
$$

where $s_p = \sum_{i=1}^{n} u_{pi}$ and $s_i = \sum_{p=1}^{m} u_{pi}$ denote the total score of the examinee $p$ and the item $i$, respectively. In order to estimate the desirable parameters $\hat{a}_p$ and $\hat{d}_i$, we need to solve the system (21)-(22), and the corresponding solution needs to satisfy the conditions (23)-(24) .

$$
\frac{\partial\Gamma}{\partial\hat{a}_p} = s_p - \sum_{i=1}^{n}\gamma_{pi} = 0, \tag{21}
$$

$$
\frac{\partial\Gamma}{\partial\hat{d}_i} = -\, s_i - \sum_{p=1}^{m}\gamma_{pi} = 0; \tag{22}
$$

$$\frac{\partial \Gamma}{\partial \hat{a}_p} = -\sum_{i=1}^{n} \gamma_{pi}(1-\gamma_{pi}) \leq 0, \tag{23}$$

$$\frac{\partial \Gamma}{\partial \hat{d}_i} = -\sum_{p=1}^{m} \gamma_{pi}(1-\gamma_{pi}) \leq 0; \tag{24}$$

where $\gamma_{pi} = \dfrac{e^{(\hat{a}_p - \bar{d}_i)}}{1+e^{(\hat{a}_p - \hat{d}_i)}}.$

An additional condition, namely $\sum_{i=1}^{n} \hat{d}_i = 0,$ , is included to the system (21) in order to have the item parameters $\hat{d}_i$ centered at zero. It is worth mentioning that the parameters obtained from (21) and (23) are not deficiency free. Indeed, these estimates assume that the person score $s_p$ is independent from the difficulty of the items in the test, and likewise the item score $s_i$ is independent from the ability distribution of the persons tested. However, none of these assumptions are generally satisfied in practice. An adjustment of the observed scores $s_p$ and $s_i$ to the corresponding item difficulty and person ability distributions are required to estimate the desirable test-free person parameters $\hat{a}_p$ and sample-free item parameters $\hat{d}_i$ (Wright and Stone, 1979)

## APPENDIX B

### Derivation of the misfit statistics for the Rasch model

For the dichotomous Rasch model, the response of person $p$ to an item $i$, $u_{pi}$, is a variable following a Bernoulli distribution, i.e. it takes only two values, for example, 0 and 1. The Rasch model estimates the probability of any instance of response $u_{pi}$ as

$$P(u_{pi}|\hat{a}_p, \hat{d}_i) = \frac{e^{(\hat{a}_p - \hat{d}_i)u_{pi}}}{1 + e^{(\hat{a}_p - \hat{d}_i)}},$$

where $\hat{a}_p$ is the estimated ability parameter of the person $p$ and $\hat{d}_i$ is the estimated difficulty parameter of item $i$.

The expected value of instances of $u_{pi}$, denoted $\hat{u}_{pi}$, is given by

$$\begin{aligned} \hat{u}_{pi} &= \mathbb{E}(u_{pi}) \\ &= P(u_{pi} = 0|\hat{a}_p, \hat{d}_i) \times 0 + P(u_{pi} = 1|\hat{a}_p, \hat{d}_i) \times 1 \\ &= \frac{e^{(\hat{a}_p - \hat{d}_i)}}{1 + e^{(\hat{a}_p - \hat{d}_i)}}. \end{aligned} \tag{25}$$

The variance of instances of $u_{pi}$, is given by

$$\begin{aligned} \text{Var}(u_{pi}) &= \mathbb{E}(u_{pi}^2) - (\mathbb{E}(u_{pi}))^2 \\ &= P(u_{pi}^2 = 0|\hat{a}_p, \hat{d}_i) \times 0 + P(u_{pi}^2 = 1|\hat{a}_p, \hat{d}_i) \times 1 - \hat{u}_{pi}^2 \\ &= \hat{u}_{pi}(1 - \hat{u}_{pi}). \end{aligned} \tag{26}$$

The residual, i.e. the difference between the observed value of $u_{pi}$ and its estimated value $\hat{u}_{pi}$, obtained via the Rasch model, is given by

$$r_{pi} = u_{pi} - \hat{u}_{pi}.$$

The standard residual, i.e. the residual divided by the expected standard deviation of instances of $u_{pi}$ obtained from (26), is given by

$$\begin{aligned} z_{pi} &= \frac{r_{pi}}{\sqrt{\hat{u}_{pi}(1-\hat{u}_{pi})}} \\ &= \frac{u_{pi}-\hat{u}_{pi}}{\sqrt{\hat{u}_{pi}(1-\hat{u}_{pi})}}. \end{aligned} \tag{27}$$

The expected value of the standard residuals, denoted $\hat{z}_{pi}$, is given by

$$\begin{aligned} \hat{z}_{pi} &= \mathbb{E}(z_{pi}) \\ &= \mathbb{E}\left(\frac{u_{pi}-\hat{u}_{pi}}{\sqrt{\hat{u}_{pi}(1-\hat{u}_{pi})}}\right) \\ &= \frac{\mathbb{E}(u_{pi})-\hat{u}_{pi}}{\sqrt{\hat{u}_{pi}(1-\hat{u}_{pi})}} \\ &= 0. \end{aligned} \tag{28}$$

The variance of the standard residuals is given by

$$\begin{aligned} \mathrm{Var}(z_{pi}) &= \mathrm{Var}\left(\frac{u_{pi}-\hat{u}_{pi}}{\sqrt{\hat{u}_{pi}(1-\hat{u}_{pi})}}\right) \\ &= \frac{\mathrm{Var}(u_{pi})}{\hat{u}_{pi}(1-\hat{u}_{pi})} \\ &= \frac{\hat{u}_{pi}(1-\hat{u}_{pi})}{\hat{u}_{pi}(1-\hat{u}_{pi})} \\ &= 1. \end{aligned} \tag{29}$$

Therefore, the standard deviation of the standard residuals, $z_{pi}$, is 1. For a large response data matrix, the standard residuals approximate a standard normal distribution with a mean of 0 and a standard deviation of 1, i.e.

$$z_{pi} \sim \mathcal{N}(0,1),$$

and consequently, the square of standard residuals approximates a chi-square distribution with one degree of freedom, i.e.

$$z_{pi}^2 \sim \chi_1^2$$

Either of the above reference distributions, i.e. N(0, 1) and $x^2_1$, can be used to assess the significance of the deviation of the standard residuals from their expected values. On the one hand, the analysis of the standard residuals enables the identification of ill-defined items, if any, which require further refinement to be in line with reasonable expectations. Furthermore, the standard residuals enable the identification of persons, if any, whose responses deviated from reasonable expectations (Wright and Stone, 1979).

**B.1 Item misfit statistics.**

The infit mean square (MNSQ) statistic for item *i*, denoted Infit $\text{MNSQ}_i$, is given by the following weighted sum of the MNSQ residuals:

$$\text{Infit MNSQ}_i = \frac{\sum_{p=1}^{m} \text{Var}(u_{pi}) z_{pi}^2}{\sum_{p=1}^{m} \text{Var}(u_{pi})}.$$

The outfit MNSQ statistic for item *i*, denoted Outfit $\text{MNSQ}_i$, is given by the unweighted sum of the MNSQ residuals:

$$\text{Outfit MNSQ}_i = \frac{\sum_{p=1}^{m} z_{pi}^2}{m}.$$

Although some of the statistical properties of the above outfit and infit statistics are not fully known, they are generally assumed to approximate a standard normal distribution (i.e. with a mean of 0 and a standard deviation of 1) in Rasch analysis literature. However, the distribution of their following cube-root transformation, suggested by Wilson and Hilferty (Wilson and Hilferty, 1931), approximate a scaled chi-squared distributions. The transformed outfit and infit statistics are referred to as the outfit $z$-standardised and the infit $z$-standardised, respectively, in Rasch analysis literature. The infit $z$-standardised statistics for item $i$, denoted Infit ZSTD$_i$, is given by

$$\text{Infit ZSTD}_i = \frac{3(k_i^{1/3} - 1)}{q_i} + \frac{q_i}{3},$$

where $k_i$ = Infit MNSQ$_i$ and $q_i$ is the standard deviation of the infit MNSQ statistic for item $i$. The outfit $z$-standardised statistics for item $i$, denoted Outfit ZSTD$_i$, is given by

$$\text{Outfit ZSTD}_i = \frac{3(\hat{k}_i^{1/3} - 1)}{\hat{q}_i} + \frac{\hat{q}_i}{3},$$

where $\hat{k}_i$ = Outfit MNSQ$_i$ and $\hat{q}_i$ is the standard deviation of the outfit MNSQ statistic for item $i$.

**B.2 Person misfit statistics**.

Like for items, the MNSQ misfit statistics for a person $p$ are given by:

$$\text{Infit MNSQ}_p = \frac{\sum_{i=1}^{n} \text{Var}(u_{pi}) z_{pi}^2}{\sum_{i=1}^{n} \text{Var}(u_{pi})}, \tag{30}$$

$$\text{Outfit MNSQ}_p = \frac{\sum_{i=1}^{n} z_{pi}^2}{n}. \tag{31}$$

The $z$-standardised misfit statistics for a person $p$ are given by:

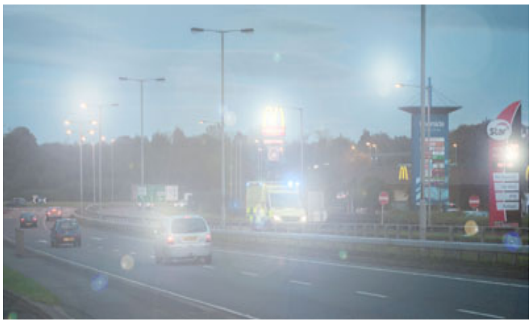
$$\text{Infit ZSTD}_p = \frac{3(k_p^{1/3} - 1)}{q_p} + \frac{q_p}{3}, \tag{32}$$

$$\text{Outfit ZSTD}_p = \frac{3(\hat{k}_p^{1/3} - 1)}{\hat{q}_p} + \frac{\hat{q}_p}{3}, \tag{33}$$

with $k_p$ = Infit $\mathrm{MNSQ}_{\mathrm{p}}$, $\hat{k}_p$ = Outfit $\mathrm{MNSQ}_p$, whereas $q_p$ and $\hat{\mathrm{q}}_{\mathrm{i}}$ are the standard deviations of the infit MNSQ and the outfit MNSQ statistic for person $p$, respectively.

## APPENDIX C

**Images used in conjunction with the QoV questionnaire.**


Glare


Haloes


Starbursts


Hazy vision


Blurred vision


Distortion


Double vision

## 3. PAPER-II

**The use of an alternative application of the Rasch model to assess the impact of lifestyle on the responses of a quality of vision questionnaire**

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**Contributions**

Richard N. McNeely – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Salissou Moutari – *concept and design, data analysis/interpretation, drafting manuscript, critical revision of manuscript, statistical analysis*

Eric Pazo – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

M. Andrew Nesbit – *critical revision of manuscript, supervision*

Tara C.B. Moore – *critical revision of manuscript, supervision*

Jonathan E. Moore – *concept and design, data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis, supervision*

**The use of an alternative application of the of the Rasch model to assess the impact of lifestyle on the responses of a quality of vision questionnaire**

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**ABSTRACT**

**Purpose:** To investigate the impact of lifestyle on the items of a quality of vision (QoV) questionnaire through an alternative application of Rasch analysis.

**Methods:** The study enrolled 503 patients receiving asymmetric multifocal intraocular lenses (IOLs). Patients completed a QoV questionnaire preoperatively and postoperative. Full examination was performed including binocular uncorrected distance (UDVA) and near (UNVA) visual acuity, contrast sensitivity, fluorescein-tear breakup time (fTBUT) and stereopsis. Preoperatively patients were categorised on their frequency of driving, and on their frequency of close work. Rasch analysis was performed on the QoV responses for the cohort of patients and then on subcategorised groups preoperatively and postoperatively. Correlation between the questionnaire items and objective clinical tests was also performed.

**Results:** Rasch analysis showed different preoperative item ordering between two lifestyle groups. Misfit statistics showed that all items were within the required range for frequent drivers, however two items misfit the model in the infrequent driver group. Postoperatively, the item ordering was different between the two lifestyle groups and the double images items misfit the model in both groups. Comparison between frequent and infrequent close work groups also showed different misfit statistics and item order, preoperatively and postoperatively. Reduced fTBUT, UNVA, dyphotopsia size and intensity was significantly associated with worse subjective responses across the overall cohort. Worse

subjective responses correlated to reduced objective performance with frequent drivers.

**Conclusions:** An alternative application of the Rasch model showed that different lifestyle groups respond differently to a QoV questionnaire and these differences correlate with other measured objective findings. This highlights shortcomings with Rasch developed ophthalmic questionnaires and that preoperative subcategorisation of patients may be required for adequate assessment of QoV.

**INTRODUCTION**

Questionnaires are now an essential aspect of clinical assessment following ophthalmic treatments and interventions. Therefore, various questionnaires have been introduced to assess a range of visual traits such as, difficulties in performing daily-life activities, visual disability or visual function.

Previously we developed an interesting and novel questionnaire to assess quality of vision (QoV) (McAlinden et al., 2010). In that paper, it was stated that various vision-related questionnaires include QoV related questions; however, these may be in combination with other latent visual traits that can affect the validity of the questionnaire. Therefore, the authors sought to develop a questionnaire to assess only QoV and it was developed using Rasch analysis. Rasch analysis is currently the most advocated approach for questionnaire development and has been widely utilised in the development (Pesudovs et al., 2004; Gupta et al., 2007; Pesudovs et al., 2006) and redevelopment (Pesudovs et al., 2003; Lamoureux et al., 2008; Lundström and Pesudovs, 2008) of various ophthalmic questionnaires.

However, recently our research has looked more closely at the specific use of Rasch analysis for this setting and have found various potential flaws related to using such an approach to validate ophthalmic questionnaires. The use of Rasch analysis for the validation of ophthalmic questionnaires seems to ignore some of the original fundamental assumptions required of the Rasch model. Rasch analysis has been used extensively to approve (Khadka et al., 2011; Garamendi et al., 2006; Khadka et al., 2013) or dismiss (McAlinden et al., 2011; McAlinden et al., 2012; Pesudovs et al., 2009) various questionnaires through misfit statistics, however this development or redevelopment of questionnaires is often performed on a single and potentially non-representative cohort of patients (Finger et al., 2012; Gothwal et al., 2010; McAlinden et al., 2011). Our recent research has highlighted that a questionnaire can be “Rasch-valid” at 1-month postoperatively and “Rasch-invalid” for the same cohort of patients 12 months postoperatively. We thus concluded that it would be prudent not to utilise Rasch analysis as traditionally used to dismiss current existing questionnaires, however by introducing an alternative approach at the population and individual level the validity of results from Rasch analysis in these questionnaires are significantly enhanced. At the population level the new approach can highlight the variation in the prevalence of symptoms across a population and therefore allows better characterisation of patient groups preoperatively and an appropriate follow-up postoperatively. At the individual level the outfit or infit parameters highlight individual patients who stand out and may require further investigation by demonstrating very different sets of symptom responses to the normal after surgical laser or lens treatments.

This study therefore sought to utilise this alternative approach of Rasch analysis to provide insights into whether lifestyle demands appear to potentially impact the subjective QoV questionnaire preoperatively, and therefore need to be subsequently subcategorised to enable the appropriate elucidation of true postoperative QoV differences through the questionnaire.

**Patients and methods**

This study recruited 503 patients who received multifocal intraocular lens (IOL) implantation. The mean age was 63, and the age range was 30 to 93. Full ophthalmic examination was performed on all patients preoperatively and postoperatively. The main postoperative objective assessments were binocular unaided distance (UDVA) and near (UNVA) visual acuities, contrast sensitivity (Pelli-Robson) and fluorescein-tear breakup time (fTBUT) and stereopsis (Titmus Fly Test). Unaided visual acuity was measured using logarithm of minimum angle of resolution (logMAR) charts for distance (6 m) and with Radner reading charts for intermediate and near vision (70cm and 40 cm).

In this study, a modified version of our previously developed QoV questionnaire (McAlinden et al., 2010) was completed preoperatively and postoperatively. The modifications included shortening the questionnaire where patients now report the presence or absence of a visual symptom item by responding either yes / no, and then report the annoyance of the symptom. Additionally, the focusing difficulties questions have been removed and replaced with a question regarding the frequency of near glasses wear. The questions included in this modified QoV questionnaire are displayed in table 1. The first seven symptom items are accompanied by a picture to aid understanding (Figure 1). The pictures utilised in this modified QoV questionnaire have been altered to represent a more realistic scene. Patients respond either not at all (0), a little (1), quite (2) or very (3) for the dysphotopsia and visual disturbance questions, and never (0), occasionally (1), quite often (2) or always (3) for the frequency of reading glasses question.

Patients were divided on the frequency of driving and close work preoperatively. Frequent drivers were considered to drive for more than 30 minutes a day and infrequent drivers less than 30 minutes a day. Similarly, frequent close work patients were considered to do more than 30 minutes a day and infrequent close work patients less than 30 minutes a day. Rasch analysis was then completed on the preoperative questionnaire data and the dimensionality of items was assessed using fit statistics. The general guidelines were followed, where values of mean-squares fit statistics greater than 1.5 suggest a deviation of the model from the unidimensionality assumption within the data, and values of mean-squares fit statistics less than 0.5 suggest an overfitting of the model. Rasch analysis with fit statistics was then completed for the overall cohort and secondly for the frequency of driving subcategories, preoperatively and postoperatively.

Additionally, the relationship / correlation between the chosen visual symptom items of the questionnaire and related objective clinical outcomes achieved by the patient were assessed. This was performed postoperatively for the overall cohort of patients. The clinical tests that were thought to correspond with the visual symptom items are shown in table 1. Patients were divided into groups depending on their ordinal responses for hazy vision, blurred vision, fluctuation in vision, frequency of reading glasses, and depth perception. The objective performance for the corresponding symptom across the four subjective response categories were then analysed. The questionnaire consists of three questions relating to dysphotopsias (Table 1). Therefore, a haloe and glare simulator (Zeiss) was also completed to assess the relationship of these visual symptom items to this objective test. The types of glare and haloes according to the simulator are displayed in figure 2. Under the supervision of an optometrist, to ensure understanding, patients adjusted the size and intensity of the glare, haloes and starbursts to reflect their everyday experience. The simulator provides a score out of 100 (0 the least, 100 the most) for the size and intensity of the symptom. A score out of 100 was recorded independently for the size and intensity of glare, haloes and starbursts. Similarly, patients were split into groups depending on their responses (not at all/a little/quite/very) for the three questions in the QoV questionnaire relating to glare, haloes and starbursts. The size and intensity for each symptom across the four subjective response categories were then analysed. To compare the effect of lifestyle on correlation between objective clinical tests and subjective responses the outcomes of the clinical tests were divided into two groups, one below the lower quartile and the other above the upper quartile, and the average 0-3 ordinal scores were compared for each group.

**Statistical analysis**

Statistical analysis was performed using SPSS for Windows (Statistical Package for the Social Sciences, Version 22, Chicago, Illinois, USA) and Excel (Microsoft; Redmond, Washington, USA). The Kolmogorov-Smirnov test was used to assess normality. The one way ANOVA with Tukey post hoc comparison procedures were utilised when assessing continuous normal data. For ordinal and non-normally distributed data, the non-parametric Mann-Whitney *U* test was applied. For all statistical analysis, the level of significance was $P<0.05$.

**Results**

The frequent driver group had a mean age of 62 ± 8.57 and the mean age of the infrequent driver group was 63 ± 9.72. There was no statistically significant difference between the age of the two groups ($P = .321$). The frequent group consisted of 61.5 % female and 38.5 % male, with the infrequent group consisting of 62.3 % female and 37.7 % male. The mean age of the frequent close work group was 62 ± 8.79 and the infrequent close work group was significantly older with a mean age of 65 ± 8.66 (P = .009). The frequent group was 59.3 % female and the infrequent group was 58.7% female.

Preoperative Rasch analysis

Table 2 outlines the item ordering of the QoV questionnaire outcomes for the overall cohort of patients preoperatively. The easiest (i.e. the most frequent) item was blurred vision and the hardest (i.e. least frequent) item was distortion. Fit statistics were all within the acceptable range of 0.50 to 1.50. The patients who were categorised as frequent drivers showed a different item ordering to the overall group, however the easiest item remained blurred vision and the hardest item remained distortion (Table 3a). Similarly, no items were found to be outside the range of fit statistics. Rasch analysis of the infrequent drivers (Table 3a) showed a different item ordering than frequent drivers and it was found that the difficulty in depth perception and double images items misfit the Rasch model for this subcategory (highlighted in red). Likewise, there was a different item order and misfit statistics for the frequency of close work groups (Table 3b).

Postoperative Rasch analysis

Table 4 outlines the item ordering of the QoV questionnaire outcomes for the overall cohort of patients postoperatively. The item ordering for the postoperative QoV responses are different from the preoperative assessment with the easiest item now glare and the hardest item distortion. Additionally, the postoperative Rasch analysis shows misfit of the model (Table 4).

Table 5 shows the Rasch analysis for the subcategorised lifestyle groups where different item ordering was found between frequent and infrequent drivers. Additionally, the double images item was found to misfit the Rasch model in both groups. Similarly, in the frequency of close work groups there was a difference in item ordering and misfit statistics (Table 5b).

Correlation of objective clinical tests and subjective visual symptom items

Table 6 displays the average outcomes for the four ordinal responses of the subjective visual symptom items across the overall cohort of patients. The different subjective responses for the hazy vision item show that patients who reported to be "not at all" affected had the best mean contrast sensitivity. The contrast sensitivity achieved decreased as the patients reported to be more affected by hazy vision. There was no statistically or clinically significant difference in UDVA for the ordinal responses. Patients who reported to be more affected by fluctuation in vision displayed a significantly shorter fTBUT and there was a significant difference between the mean UNVA and the subjective responses. Additionally, table 6 outlines that there was a significant difference in the objective outcomes reported by the haloe and glare simulator for each dysphotopsia across the different ordinal responses.

Table 7 displays the average ordinal responses for the lower and upper quartiles of the corresponding clinical objective tests, for the two separate lifestyle groups. The subjective ordinal response regarding fluctuation in vision is significantly worse for patients with a shorter fTBUT in the frequent driver group, however there is no significant difference in the infrequent driver group. Similarly, table 8 shows the results for the dysphotopsia questions where subjective responses are significantly worse with reduced objective performance in the frequent driver group however no significant difference was observed in the infrequent driver group, except for starburst size.

**Discussion**

Questionnaires are now viewed as an important part of the clinical assessment following ophthalmic treatment or intervention (Pesudovs, 2006; Lundström and Pesudovs, 2011). Many questionnaires have subsequently been introduced and the methodology used to develop such questionnaires has evolved over the years. The early ophthalmic questionnaires were developed using classical test theory (CTT) where ordinal responses were summed to provide an overall score (Hays et al., 2003; Pesudovs, 2006; Lundström and Pesudovs, 2011; Schein, 2000). However, the shortcomings of CTT were realised and the development of questionnaires are now commonly performed by item response theory (IRT). Rasch analysis, which can be viewed as a particular IRT, is the primary method for questionnaire development. It has been found that questionnaires developed or rescaled with Rasch analysis produce better quality scales compared to those produced by CTT (Kandel et al., 2017), and if a questionnaire is to be used clinically or if one is seeking to develop a questionnaire, Rasch analysis should be used (Lundström and Pesudovs, 2011). However, our previous study outlines various shortcomings of Rasch analysis with regards to analysis of the QoV questionnaire and potentially also for various other questionnaires utilised within ophthalmology. Rather than dispensing with Rasch analysis in the analysis of the QoV questionnaire we found that its use can be enhanced through a process of stratification of patients to ensure that patient groups with similar preoperative Rasch characteristics can subsequently be compared after different interventions. This process maximises the potential value of Rasch analysis by utilising it as a decision support tool at both population and individual level to enable characterisation of the prevalence of symptoms across patient groups preoperatively. This will therefore enable the subsequent stratification of patients, based upon these results, to be separately analysed postoperatively rather than assessing patients purely as a homogenous group. Additionally, the process facilitates the highlighting of specific patients who are significantly affected and may require further care. It is recognised that patients' personality, their work and various social related visual demands can impact their responses to questionnaires designed to define either their QoV or the impact of vision upon their quality of life. Therefore, this study sought to use this new application of Rasch analysis to determine if the item ordering and fit statistics remained the same at the population level between subcategorised lifestyle groups. In this study, Rasch analysis was first performed preoperatively on the overall cohort of patients (Table 2) and then applied to the separate lifestyle groups (Table 3). Rasch analysis arranges the items from easiest to hardest (frequency of answers) and determines that the instrument measures a unidimensional trait through misfit statistics. Rasch analysis provides a linear scale of a unidimensional trait so that patients and treatments can be compared. However, through our alternative application of the Rasch model, which enables one to investigate the prevalence of ophthalmic symptoms across a cohort of patients, it is evident that the item ordering and misfit statistics preoperatively is dependent on lifestyle demands. Initially our analysis showed the item ordering and misfit statistics for the overall cohort of patients (Table 2). Then analysis of frequent and infrequent lifestyle groups highlighted the difference in item ordering and misfit statistics to the overall cohort of patients and between the lifestyle groups (Table 3). The item ordering produced by Rasch analysis which provides a linear scale is not constant for different patient groups and therefore in theory cannot be used to compare patient groups as it is designed to do. The use of Rasch analysis without defining patient subcategories that display different item ordering preoperatively does not allow adequate assessment of the trait because the cohort will include patients who react differently to the trait under investigation, in this case QoV. Currently, Rasch analysis is utilised on a single cohort of patients, and in many cases the cohort is relatively small (Finger et al., 2012; Gothwal et al., 2009a; Gothwal et al., 2010; McAlinden et al., 2011; Huang et al., 2017; Khadka et al., 2011). However, it is clear from our study that lifestyle has an impact on the QoV reported with this questionnaire and QoV is not universal across an overall cohort with different subjective visual symptom items being more common depending on the frequency of driving or close work. Therefore, utilising Rasch analysis without understanding the item ordering and therefore subcategorising patients into groups with similar preoperative item ordering does not allow adequate comparison of postoperative results and comparison to other studies. Additionally, because of the high standard errors in QoV outcomes results of studies will lack power and it will therefore be hard to accurately determine the effect of treatments or interventions on subjective outcomes because similar groups will not be compared. Therefore, to improve the use of the QoV questionnaire, and other ophthalmic questionnaires, the use of our alternative application of Rasch analysis is required to determine different preoperative subcategories. Defining preoperative groups based on lifestyle, or other groups, through item ordering allows a more accurate assessment of the trait under investigation because subcategories with the same item ordering can be identified. Similar to our previous study, that showed the differences in QoV responses between two postoperative assessments following asymmetric multifocal IOL implantation, it was found in this study that the item ordering and misfit statistics of the overall cohort of patients and the individual lifestyle groups differed between preoperative and postoperative assessment.

Furthermore, this study attempted to assess the correlation between the subjective visual symptom items and objective clinical tests to further assess whether the impact of lifestyle on QoV responses found via Rasch analysis is also reflected in the objective clinical findings, and to further corroborate the need for subcategorisation of preoperative groups. Initially the correlation between the objective and subjective outcomes were assessed in the overall cohort of patients. It was found that patients who report to be “not at all” affected by the visual symptom item show a superior average performance with the corresponding objective clinical test (Table 6). As patients report to be increasingly more affected by the questioned symptom their mean objective performance reduces. After demonstrating this association, we sought to further highlight the importance of subcategorisation preoperatively by analysing the effect of lifestyle on the correlation between objective and subjective outcomes. It was found that the frequent driver group showed a significant difference in their subjective performance when a reduced objective performance was observed, however there was no significant difference in subjective findings in the same comparison for infrequent drivers. (Table 7 & 8). It appears that infrequent drivers are more tolerant to worse objective outcomes as they do not report a significant difference in subjective ordinal responses between different objective performances. This study highlights the difference between lifestyle groups in item ordering and misfit statistics of a QoV questionnaire and it appears that this is also observed in a different correlation between the objective clinical tests and subjective visual symptom items in the frequency of driving groups. Therefore, it is clear from the different Rasch characteristics and correlation between objective and subjective outcomes that lifestyle demands often creates unique patient groups and to compare them in one homogenous group would introduce error. It is not currently standard practice to subcategorise patients on lifestyle demands when assessing various ophthalmic treatments, such as IOL implantation. However, when comparing different treatments and interventions it is well acknowledge that patient groups should be similar (e.g. age and sex matching) to allow an accurate comparison. This study, further highlights the shortcomings of a Rasch analsysed QoV questionnaire and it, therefore, may be important to subcategorise on lifestyle demands before assessing QoV outcomes of IOLs so like groups can be assessed separately and to enable one to make meaningful comparisons to other studies. This study highlights a methodology that can be used for preoperative subcategorisation, and clinicians should use this analysis to enhance subjective questionnaire outcomes by detecting distinct patient groups. This approach should be useful for assessing the effect of other lifestyle demands, or indeed other patient groups such as myopes or hyperopes.

A limitation of this study was that not all visual symptom items were assessed. Assessment of distortion with the Amsler chart may be related to patients' perception of distortion, however this test was not performed on this cohort of patients and it may be useful to assess this in our future work. To our understanding there is no test to assess monocular double vision, which would be required to assess this symptom accurately in multifocal IOL patients. However, in an attempt to investigate this, we assessed the impact of stereopsis on double vision and no correlation was found. Similarly, stereopsis was used to assess depth perception and again no correlation was found. Additionally, further analysis of other lifestyle and / or patient groups is necessary to further investigate the shortcomings of Rasch in subjective questionnaires.

In conclusion, this study highlights that performing Rasch analysis without defining different groups preoperatively dependent on item ordering and misfit statistics affects the outcomes of a QoV questionnaire. Subcategorisation on lifestyle demands was found to be important for the use of this QoV questionnaire because the item ordering and misfit statistics of the same questionnaire varied for different lifestyle groups. Therefore, understanding the item ordering preoperatively on lifestyle groups, or on other groups, allows one to factor this into postoperative assessment by grouping patients together who have a similar preoperative response to the trait under investigation and therefore allows a more accurate comparison between treatments and other studies.

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## FIGURES & TABLES

**Figure 1 -** Quality of vision pictures used with the first seven items

**Figure 2 -** Types of haloes (H1, H2 and H3), and types of glare (G1 and G2) according to the simulator used in the study, the Halo & Glare Simulator (Zeiss).

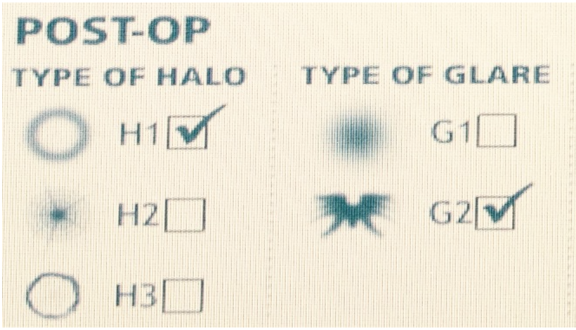

**Table 1 –** The questions of the QoV questionnaire and the corresponding clinical tests.

| Item number | Question | Clinical test |
|---|---|---|
| 1 | Do you experience glare? | Haloe and glare simulator |
| 2 | How much does the glare bother you? | |
| 3 | Do you experience haloes? | Haloe and glare simulator |
| 4 | How much do the haloes bother you? | |
| 5 | Do you experience starbursts? | Haloe and glare simulator |
| 6 | How much do the starbursts bother you? | |
| 7 | Do you experience hazy vision? | Contrast sensitivity |
| 8 | How much does the hazy vision bother you? | |
| 9 | Do you experience blurred vision? | UDVA (logMAR) |
| 10 | How much does the blurred vision bother you? | |
| 11 | Do you experience distortion? | |
| 12 | How much does the distortion bother you? | |
| 13 | Do you experience double vision? | |
| 14 | How much does the double vision bother you? | |
| 15 | How often does your vision fluctuate? | fTBUT (seconds) |
| 16 | Does the fluctuation bother you? | |
| 17 | Reading glasses to focus on near object? | UNVA (logMAR) |
| 18 | Difficulty in depth perception? | |
| 19 | How often is depth perception a bother? | |
| 20 | Overall QoV score (0-10) | |

**Table 2** – Rasch analysis of preoperative questionnaire data for the overall cohort of patients.

| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
|---|---|---|---|---|
| Blurred vision | -0.89 | 0.09 | 0.8 | 0.85 |
| Glare | -0.78 | 0.09 | 0.93 | 0.91 |
| Hazy vision | -0.47 | 0.09 | 0.79 | 0.88 |
| Fluctuation | -0.39 | 0.1 | 1.03 | 1.02 |
| Starbursts | -0.11 | 0.11 | 1.09 | 1.08 |
| Haloes | 0.05 | 0.11 | 0.75 | 1.02 |
| Difficulty in depth perception | 0.08 | 0.11 | 1.46 | 1.37 |
| Double images | 1.14 | 0.17 | 1.13 | 1.21 |
| Distortion | 1.37 | 0.19 | 0.7 | 1.32 |

**Table 3** – Rasch analysis of preoperative questionnaire data for (A) frequent and infrequent drivers (B) frequent and infrequent close work patients.

A

| **FREQUENT DRIVERS** | | | | |
|---|---|---|---|---|
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Blurred vision | -0.87 | 0.1 | 0.87 | 0.92 |
| Glare | -0.75 | 0.1 | 0.91 | 0.89 |
| Hazy vision | -0.48 | 0.11 | 0.78 | 0.84 |
| Fluctuation | -0.37 | 0.11 | 1.07 | 1.06 |
| Difficulty in depth perception | -0.07 | 0.12 | 1.41 | 1.35 |
| Starbursts | -0.06 | 0.12 | 1.15 | 1.16 |
| Haloes | 0.18 | 0.13 | 0.66 | 0.95 |
| Double images | 1.1 | 0.19 | 0.92 | 1.14 |
| Distortion | 1.3 | 0.21 | 0.72 | 1.39 |
| **INFREQUENT DRIVERS** | | | | |
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Blurred vision | -1.06 | 0.18 | 0.6 | 0.66 |
| Glare | -0.99 | 0.18 | 0.99 | 1 |
| Hazy vision, Fluctuation | -0.54 | 0.21 | 0.83 | 1.04 |
| Haloes | -0.41 | 0.21 | 0.91 | 1.22 |
| Starbursts | -0.32 | 0.22 | 0.93 | 0.87 |
| Difficulty in depth perception | 0.88 | 0.34 | 1.51 | 1.21 |
| Double images | 1.29 | 0.41 | 2.27 | 1.5 |
| Distortion | 1.7 | 0.5 | 0.65 | 0.81 |

B

| FREQUENT CLOSE WORK | | | | |
|---|---|---|---|---|
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Glare, Blurred vision | -0.88 | 0.1 | 0.95 | 0.94 |
| Fluctuation | -0.52 | 0.11 | 1.02 | 1.06 |
| Hazy vision | -0.5 | 0.11 | 0.75 | 0.81 |
| Starbursts | -0.21 | 0.12 | 1 | 0.95 |
| Haloes | 0.01 | 0.13 | 0.71 | 1.03 |
| Difficulty in depth perception | 0.19 | 0.14 | 1.68 | 1.58 |
| Double images | 1.08 | 0.21 | 1.17 | 1.32 |
| Distortion | 1.7 | 0.28 | 0.71 | 1.45 |
| **INFREQUENT CLOSE WORK** | | | | |
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Blurred vision | -1.02 | 0.17 | 1.04 | 1.1 |
| Glare | -0.59 | 0.18 | 0.71 | 0.79 |
| Hazy vision | -0.49 | 0.18 | 0.94 | 1.09 |
| Difficulty in depth perception | -0.2 | 0.2 | 1.06 | 0.93 |
| Fluctuation | -0.08 | 0.2 | 0.94 | 0.79 |
| Haloes | 0.09 | 0.21 | 0.88 | 1.01 |
| Starbursts | 0.14 | 0.22 | 1.26 | 1.42 |
| Distortion | 0.9 | 0.28 | 0.83 | 1.12 |
| Double images | 1.25 | 0.32 | 0.97 | 1.01 |

**Table 4** – Rasch analysis of postoperative questionnaire data for the overall cohort of patients.

| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
|---|---|---|---|---|
| Glare | -1.04 | 0.07 | 0.78 | 0.78 |
| Starbursts | -0.81 | 0.08 | 0.97 | 1.01 |
| Fluctuation | -0.77 | 0.08 | 0.94 | 0.93 |
| Haloes | -0.56 | 0.08 | 0.98 | 1.01 |
| Blurred vision | -0.43 | 0.08 | 0.92 | 0.96 |
| Hazy vision | -0.18 | 0.09 | 0.86 | 1.06 |
| Double images | 0.56 | 0.12 | 1.32 | 1.59 |
| Difficulty in depth perception | 0.95 | 0.14 | 1.12 | 1.35 |
| Distortion | 2.27 | 0.25 | 0.84 | 1.57 |

**Table 5** – Rasch analysis of postoperative questionnaire data for (A) frequent and infrequent drivers (B) frequent and infrequent close work patients

A

| **FREQUENT DRIVERS** | | | | |
|---|---|---|---|---|
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Glare | -1.1 | 0.08 | 0.81 | 0.79 |
| Starbursts | -0.91 | 0.08 | 0.97 | 1.01 |
| Fluctuation | -0.68 | 0.09 | 0.91 | 0.9 |
| Haloes | -0.56 | 0.09 | 0.93 | 1.02 |
| Blurred vision | -0.3 | 0.1 | 0.91 | 0.97 |
| Hazy vision | -0.17 | 0.1 | 0.87 | 1.05 |
| Double images | 0.63 | 0.14 | 1.31 | 1.57 |
| Difficulty in depth perception | 0.94 | 0.15 | 1.12 | 1.41 |
| Distortion | 2.16 | 0.26 | 0.87 | 1.6 |
| **INFREQUENT DRIVERS** | | | | |
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Fluctuation | -1.21 | 0.16 | 0.99 | 1.03 |
| Blurred vision | -0.94 | 0.17 | 0.86 | 0.85 |
| Glare | -0.89 | 0.17 | 0.61 | 0.72 |
| Haloes | -0.67 | 0.18 | 1.2 | 1 |
| Starbursts | -0.47 | 0.19 | 0.92 | 0.9 |
| Hazy vision | -0.27 | 0.21 | 0.84 | 1.13 |
| Double images | 0.24 | 0.25 | 1.35 | 1.74 |
| Difficulty in depth perception | 0.98 | 0.34 | 1.19 | 1.12 |
| Distortion | 3.23 | 1 | 0.61 | 1 |

**B**

| FREQUENT CLOSE WORK | | | | |
|---|---|---|---|---|
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Glare | -1.08 | 0.08 | 0.72 | 0.72 |
| Fluctuation | -0.88 | 0.08 | 0.92 | 0.91 |
| Starbursts | -0.85 | 0.08 | 1.03 | 1.03 |
| Haloes | -0.57 | 0.09 | 1.06 | 1.07 |
| Blurred vision | -0.49 | 0.09 | 0.87 | 0.96 |
| Hazy vision | -0.12 | 0.1 | 0.81 | 1.07 |
| Double images | 0.49 | 0.13 | 1.41 | 1.61 |
| Difficulty in depth perception | 0.85 | 0.15 | 1.08 | 1.33 |
| Distortion | 2.65 | 0.36 | 1 | 1.24 |
| **INFREQUENT CLOSE WORK** | | | | |
| **Items** | **Item Difficulties** | **Standard Error** | **Outfit MNSQ** | **Infit MNSQ** |
| Glare | -0.98 | 0.17 | 1.03 | 1.05 |
| Starbursts | -0.77 | 0.18 | 0.79 | 0.95 |
| Haloes | -0.65 | 0.18 | 0.72 | 0.76 |
| Hazy vision | -0.47 | 0.19 | 0.96 | 1.03 |
| Fluctuation | -0.4 | 0.19 | 1.05 | 1 |
| Blurred vision | -0.28 | 0.2 | 1.13 | 0.94 |
| Double images | 0.71 | 0.28 | 0.96 | 1.51 |
| Difficulty in depth perception | 1.29 | 0.34 | 1.31 | 1.37 |
| Distortion | 1.55 | 0.38 | 0.65 | 1.76 |

**Table 6 -** Between-group comparison of the objective clinical outcomes for the different postoperative subjective questionnaire responses across the overall cohort of patients.

| | **Not at all/Never** | **A little /occasionally** | **Quite/Quite often** | **Very/Always** | **P Value** |
|---|---|---|---|---|---|
| **Contrast sensitivity found in Hazy vision categories** | 1.46 ± 0.14 | 1.46 ± 0.15 | 1.41 ± 0.13 | 1.31 ± 0.08 | .106 |
| **UDVA (logMAR) found in Blurred vision categories** | -0.05 ± 0.05 | -0.05 ± 0.09 | -0.05 ± 0.10 | -0.03 ± 0.08 | .859 |
| **fTBUT (seconds) in Fluctuation categories** | 6.19 ± 2.19 | 5.13 ± 1.59 | 4.78 ± 1.88 | 4.67 ± 1.44 | <.001 |
| **UNVA (logMAR) found in Reading glasses categories** | 0.11 ± 0.11 | 0.16 ± 0.11 | 0.2 ± 0.13 | 0.23 ± 0.17 | <.001 |
| **Glare Size (0-100, Haloe and glare simulator)** | 27.33 ± 16.39 | 31.29 ± 16.63 | 39.53 ± 13.63 | 50.00 ± 14.57 | .004 |
| **Glare Intensity (0-100, Haloe and glare simulator)** | 46.72 ± 14.28 | 43.42 ± 16.83 | 45.6 ± 13.68 | 51.75 ± 23.89 | .609 |
| **Haloe Size (0-100, Haloe and glare simulator)** | 30.38 ± 10.90 | 40.44 ± 15.58 | 45.22 ± 15.67 | 64.00 ± 21.16 | <.001 |
| **Haloe Intensity (0-100, Haloe and glare simulator)** | 48.19 ± 13.50 | 51.22 ± 15.65 | 55.11 ± 21.90 | 70.57 ± 14.70 | .012 |
| **Starbursts Size (0-100, Haloe and glare simulator)** | 34.74 ± 13.69 | 42.47 ± 13.79 | 51.67 ± 12.53 | 59.33 ± 23.71 | <.001 |
| **Starbursts Intensity (0-100, Haloe and glare simulator)** | 52.11 ± 17.13 | 52.95 ± 16.30 | 60.13 ± 12.40 | 70.56 ± 19.70 | .015 |

**Table 7 -** Comparison of the average ordinal responses in the lower and upper quartiles of the objective outcomes for frequent and infrequent drivers.

| | **Contrast Sensitivity** | | | **UDVA (logMAR)** | | | **fTBUT (secs)** | | |
|---|---|---|---|---|---|---|---|---|---|
| | Lower Quartile | Upper Quartile | P Value | Lower Quartile | Upper Quartile | P Value | Lower Quartile | Upper Quartile | P Value |
| **Frequent drivers** | | | | | | | | | |
| **Subjective score (0-3)** | 0.19 ± 0.51 | 0.16 ± 0.46 | .771 | 0.31 ± 0.65 | 0.45 ± 0.85 | .401 | 0.21 ± 0.54 | 1.00 ± 1.15 | .001 |
| **Infrequent drivers** | | | | | | | | | |
| **Subjective score (0-3)** | 0.43 ± 1.13 | 0.10 ± 0.32 | .887 | 0.24 ± 0.62 | 0.31 ± 0.63 | .727 | 0.20 ± 0.77 | 0.60 ± 0.84 | .216 |

**Table 8 -** Comparison of the average ordinal responses in the lower and upper quartiles of the simulator scores for frequent and infrequent drivers.

| | **Glare Size (0-100)** | | | **Haloe Size (0-100)** | | | **Starburst Size (0-100)** | | |
|---|---|---|---|---|---|---|---|---|---|
| | Lower Quartile | Upper Quartile | P Value | Lower Quartile | Upper Quartile | P Value | Lower Quartile | Upper Quartile | P Value |
| **Frequent drivers** | | | | | | | | | |
| **Subjective score (0-3)** | 0.38 ± 0.51 | 1.67 ± 1.18 | .001 | 0.54 ± 0.66 | 1.92 ± 0.90 | .001 | 0.56 ± 0.81 | 1.62 ± 0.96 | .002 |
| **Infrequent drivers** | | | | | | | | | |
| **Subjective score (0-3)** | 1.00 ± 0.71 | 1.60 ± 1.14 | .421 | 0.50 ± 0.58 | 1.60 ± 0.89 | .111 | 0.67 ± 0.58 | 2.40 ± 0.55 | .036 |
| | **Glare Intensity (0-100)** | | | **Haloe Intensity (0-100)** | | | **Starburst Intensity (0-100)** | | |
| | Lower Quartile | Upper Quartile | P Value | Lower Quartile | Upper Quartile | P Value | Lower Quartile | Upper Quartile | P Value |
| **Frequent drivers** | | | | | | | | | |
| **Subjective score (0-3)** | 0.85 ± 0.69 | 1.14 ± 1.03 | .583 | 0.85 ± 0.69 | 1.67 ± 1.15 | .087 | 0.88 ± 0.86 | 1.76 ± 1.15 | .029 |
| **Infrequent drivers** | | | | | | | | | |
| **Subjective score (0-3)** | 0.80 ± 0.45 | 1.20 ± 0.84 | .421 | 0.60 ± 0.89 | 0.83 ± 1.17 | .792 | 0.20 ± 0.45 | 1.00 ± 0.82 | .190 |

**4. PAPER-III**

**Visual outcomes and patient satisfaction three and twelve months after implantation of a refractive rotationally asymmetric multifocal intraocular lens**

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**Contributions**

Richard N. McNeely – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Eric Pazo – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Andrew Spence – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

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M. Andrew Nesbit – *critical revision of manuscript, supervision*

Tara C.B. Moore – *critical revision of manuscript, supervision*

Jonathan E. Moore – *concept and design, data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis, supervision*

**Visual outcomes and patient satisfaction three and twelve months after implantation of a refractive rotationally asymmetric multifocal intraocular lens**

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## ABSTRACT

**Purpose:** To assess the 3-month and 12-month postoperative visual performance and subjective patient satisfaction after refractive lens exchange (RLE) with implantation of a rotationally asymmetric multifocal intraocular lens (IOL).

**Setting/Venue:** Cathedral Eye Clinic, Belfast, United Kingdom.

**Design:** Prospective case series.

**Methods:** The refraction, uncorrected (UDVA) and corrected distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, distance-corrected intermediate and near visual acuities, and a quality of vision (QoV) questionnaire were evaluated 3 months and 12 months after implantation of an SBL-3 IOL.

**Results:** The study enrolled 100 eyes of 50 patients. The mean monocular UDVA was - 0.02 logarithm of minimum angle of resolution (logMAR) ± 0.12 (SD) 3 months postoperatively and - 0.01 ± 0.10 logMAR at 12 months ($P = .393$). The mean monocular UIVA was 0.39 ± 0.11 logMAR and 0.41 ± 0.12 logMAR, respectively ($P = .06$). The mean monocular UNVA was 0.12 ± 0.13 logMAR and 0.14 ± 0.12 logMAR, respectively ($P = .077$). The mean QoV score was 8.26 ± 1.16 at 3 months with a significant improvement at 12 months, at which time the mean QoV score was 8.84 ± 1.08 ($P \leq .001$).

**Conclusions:** This asymmetric multifocal IOL provided excellent unaided vision with no significant difference in near, intermediate, and distance vision 3 months and 12 months postoperatively. However, there was a significant improvement in subjective outcomes at the second postoperative assessment, during which patients reported a significantly better QoV score and less blurred vision.

**INTORDUCTION**

Refractive rotationally asymmetric multifocal intraocular lenses (IOLs) are now widely accepted as an effective method to treat presbyopia after cataract extraction surgery or refractive lens exchange (RLE). Rotationally asymmetric multifocal IOLs have 2 distinct zones; that is, a distance zone and a near zone. This differs from the traditional rotationally symmetrical multifocal IOLs, which consist of concentric rings to provide multifocality.

The Lentis Mplus (Oculentis GmbH) was the first rotationally asymmetric multifocal IOL, and various studies (Alió et al., 2012a; Ramón et al., 2012; Alió et al., 2011a; McAlinden and Moore, 2011; Alió et al., 2012b) have outlined the excellent vision achieved at various distances and a high level of subjective patient satisfaction with reduced dysphotopsias and improved contrast sensitivity compared with some diffractive multifocal IOLs. Another rotationally asymmetric multifocal IOL, the SBL-3 (Lenstec, Inc.), has been developed. In the United States, this IOL is being evaluated at present under IDE G140134 and Clinical Trials NCT02487160 (A) in a prospective multicenter masked randomized 2-arm parallel group study. Subjects are enrolled after meeting strict inclusion and exclusion criteria and are followed for up to 1 year. An initial study by Venter et al., (2014) outlined the 3-month postoperative predictability, visual outcomes, and patient satisfaction of this new rotationally asymmetric IOL. However, to our knowledge this is the only study of this multifocal IOL published at present; therefore, there are no studies of the performance of this IOL over a longer postoperative period.

This study sought to determine the visual performance and patient satisfaction after bilateral implantation of the new rotationally asymmetric multifocal IOL up to 1 year postoperatively. The goal was to determine whether or how the visual performance of the IOL and the subjective quality of vision (QoV) perceived by patients alter over time.

**Patients and methods**

This prospective consecutive case series recruited patients receiving SBL-3 bilateral rotationally asymmetric multifocal IOLs after RLE. All patients gave informed consent for their anonymised data to be submitted for audit and publication, and the possible risks of the operation and the possible need for further laser refractive surgery were explained. Patients who developed posterior capsule opacification or who had active ocular disease were excluded from the study.

**Patient Assessment**

All patients had a full preoperative ophthalmologic assessment. The examination included a medical history, keratometry, topography, and autorefraction (OPD-Scan II ARK-10000, Nidek Co., Ltd.), subjective refraction (RT-5100 Auto Phoropter Head, Nidek Co., Ltd.), slitlamp evaluation, Goldmann tonometry, dilated fundoscopy, and retinal optical coherence tomography (Cirrus 4000, Carl Zeiss Meditec AG). Biometry performed with the IOLMaster

(Carl Zeiss Meditec AG) measured corneal curvature, anterior chamber depth, and axial length (AL) for subsequent IOL calculation. The Hoffer Q formula (Hoffer,

2007) was used for eyes with an AL of less than 22.0 mm, and the SRK/T formula (Retzlaff et al., 1990) was used for ALs of 22.0 mm or more. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, and distance-corrected intermediate and near visual acuities were measured using logarithm of minimum angle of resolution (logMAR) charts for distance (6 m) and with Radner reading charts for intermediate and near vision (70 cm and 40 cm).

The postoperative assessments were performed at 3 months and 12 months. They included the same assessments as the preoperative examination with the main postoperative measurements including UDVA, UNVA, and UIVA. The rotational position of the IOL was assessed at each postoperative visit to confirm inferonasal placement of the near segment.

To assess postoperative subjective patient satisfaction, a previously developed QoV questionnaire (McAlinden et al., 2010) was completed. The QoV questionnaire determined how bothered the patients were by various visual disturbances and photopic phenomenon. The patients responded to each question with not at all (0), a little (1), quite (2), or very (3). The QoV questionnaire has a 0 to 10 overall QoV score, with 0 being the worst and 10 the best. This provides a linear subjective score of how each individual rates his or her overall vision. In addition to the QoV questionnaire, patients were asked how often they required reading spectacles. Patients responded with never (0), occasionally (1), quite often (2), or always (3). Patients were also asked to report the quality of their intermediate vision by responding with clear, slight problem, moderate problem, severe problem, or intolerable problem.

**Intraocular Lens**

Venter et al., (2014) outlined the design and characteristics of the new asymmetric multifocal IOL. It is a bi-aspheric asymmetric refractive multifocal IOL with 2 distinct zones. One zone is for distance vision, and the other is a +3.00 diopter (D) near segment with a wedge shaped transition zone. The near segment occupies 42% of the IOL. The IOL has an overall length of 11.00 mm with a 5.75 mm optic. It is of a hydrophilic acrylic material and has a neutral aberration profile.

**Surgical Technique**

Standard on-axis clear corneal phacoemulsification surgery was performed by the same experienced surgeon (J.E.M.) in all cases. To avoid the introduction of oblique astigmatism and reduce the likelihood of an increase in postoperative corneal astigmatism, a 2.75 mm incision was made at the steepest meridian. In all cases, the surgery was performed under sub-Tenon or topical anesthesia. A 5.00 mm anterior capsulorhexis was created and the multifocal IOL implanted in the capsular bag. The vertical axis (reading segment) of the IOL was positioned inferiorly with slight nasal deviation. The refractive aim was emmetropia.

**Statistical Analysis**

Statistical analysis was performed using SPSS for Windows software (version 22, Statistical Package for the Social Sciences, Inc.) and Excel software (Microsoft Corp.). Initially, the Kolmogorov-Smirnov test was used to assess normality of the data. When comparing the data between the 2 postoperative assessments, the Student t test for paired data was used for parametric analysis. For assessing nonparametric data, the Wilcoxon rank-sum test was used. The level of significance was a P value less than 0.05.

**Results**

One hundred eyes of 50 patients were included in the study. Table 1 shows the patients' demographics and the preoperative examination results.

**Visual Acuity and Refraction**

Table 2 shows a comparison of the objective visual and refractive results between the 3-month and 12-month postoperative assessments. Figure 1, A, B, and C, shows the cumulative monocular UDVA, UIVA, and UNVA, respectively, at each postoperative assessment. Figure 2 shows the changes in CDVA Snellen lines postoperatively, and figure 3 the difference between postoperative UDVA and CDVA.

Figure 4 shows the accuracy of the attempted spherical equivalent (SE) correction at 3 months and 12 months. Eighty-six eyes (86%) at 3 months and 82 eyes (82%) at 12 months were within ±0.50 D of emmetropia. Ninety-nine eyes (99%) and 98 eyes (98%) were within ±1.00 D of emmetropia at the 2 respective follow-up assessments. Figure 5 shows the postoperative refractive cylinder at the two postopertaive assessments.

Figure 6 shows the stability of the SE up to 12 months postoperatively. Ninety-eight eyes (98%) had a change in SE refraction of 1.00 D or less between 3 months and 12 months.

**Overall Satisfaction and Spectacle Independence**

The preoperative mean QoV score was 8.05 ± 1.36 (range 5 to 10), and an improvement was observed at each postoperative assessment. Figure 7 shows the overall QoV scores for the 2 postoperative assessments. There was a statistically significant improvement in the postoperative QoV from 3 months to 12 months ($P \leq .001$, paired t test). Additionally, it was found that no patient reported worse QoV at the second postoperative assessment.

There was no significant difference in spectacle independence and the percentage of responses between the 2 assessments (Figure 8).

In addition, 39 (78%) of 50 patients reported their intermediate vision was clear and 45 patients (90%) reported their intermediate vision was either clear or a slight problem to them at the 3-month assessment. At the second postoperative assessment 43 (86%) of 50 patients reported clear intermediate vision and 48 (96%) patients reported their intermediate vision was clear or only a slight problem.

**Visual Disturbances and Photopic Phenomena**

Table 3 shows the subjective responses from both postoperative assessments. Patients were statistically significantly less affected by blurred vision 12 months postoperatively than they were 3 months postoperatively.

**Discussion**

Multifocal IOLs using diffractive or refractive optics through a range of concentric rings have been used since the early 1990s. However, approximately 7 years ago, a new design of refractive multifocal IOL that consisted of 2 distinct zones was introduced. One zone was for distance vision and the other for near vision, creating a rotationally asymmetric multifocal IOL. Several studies (Alió et al., 2012c; Rosa et al., 2013; van der Linden et al., 2012) report the outcomes with the first commercially available asymmetric multifocal IOL. A second asymmetric multifocal IOL has since been introduced, and an initial study (Venter et al., 2014) showed this IOL provided excellent results up to 3 months postoperatively.

This present study sought to determine the objective and subjective outcomes after bilateral implantation of the new asymmetric multifocal IOL up to a longer postoperative time point than in previous studies. This study sought to compare objective and subjective parameters 3 months and 12 months postoperatively to determine how they alter, if at all, over this period.

In this study, visual and refractive outcomes at both postoperative assessments showed excellent unaided visual acuity. The mean UDVA was -0.02 logMAR ± 0.12 (SD) and -0.01 ± 0.10 logMAR at the 2 respective postoperative assessments. These findings were similar to the results of Venter et al., (2014) 3 months after bilateral implantation of the new asymmetric multifocal IOL. Our study also had better postoperative UDVA results than studies that evaluated the postoperative outcomes after bilateral implantation of the first asymmetric multifocal IOL. (Alió et al., 2011a; Muñoz et al., 2011) In addition, in this study there was no statistically significant difference in the UDVA between the 2 assessments; 77 eyes (77%) and 71 eyes (71%), respectively, achieved a monocular UDVA of 6/6 (0.0 logMAR) or better. These UDVA findings are better than those in a study of bilateral implantation of the first asymmetric multifocal IOL up to 6 months postoperatively (Venter et al., 2013). The UIVA results found in this study was worse than those found by Venter et al., (2014) 3 months after implantation of the new asymmetric IOL. Likewise, the UIVA results in this study were worse than the results observed with the first asymmetric multifocal IOL 6 months postoperatively (Muñoz et al., 2011). However, when asked about the quality of their intermediate vision, 45 patients (90%) in our study reported clear or a slight problem 12 months postoperatively. This shows that the asymmetric multifocal IOL in this study provided good functional intermediate vision. There was no significant difference between the 2 assessments in UIVA.

Comparing the mean monocular UNVA with the initial asymmetric multifocal IOL study (Venter et al., 2014) again showed outcomes comparable to both postoperative assessments in our study. The observed mean monocular UNVA was also better than that in other studies of bilateral implantation of the first asymmetric multifocal IOL (Alió et al., 2012a; Alió et al., 2011b). For the monocular UNVA in our study, 95 eyes (95%) and 90 eyes (90%) achieved 6/12 (0.30 logMAR) at the 2 respective postoperative assessments, which was better than that observed by Venter et al., (2014).

The excellent functional intermediate vision and unaided near visual acuity were most likely the result of the smooth transition between the 2 zones of the IOL, with additional depth of focus produced through residual corneal spherical aberration (Venter et al., 2014). This study did not analyze the effect of higher order aberrations on depth of focus, and future studies to assess this would be beneficial. In addition, further comparative studies with other multifocal IOLs, such as the first asymmetric multifocal IOL and rotationally symmetrical multifocal IOLs, would allow for further discussion regarding the intermediate and near vision achieved with this IOL.

In this current study, the level of safety was excellent. At the second postoperative assessment, 1 eye lost 2 lines of CDVA; however, this eye had early posterior capsular opacification but was not treated because CDVA was 0.0 logMAR. In addition, 15 eyes (15%) at 3 months and 22 eyes (22%) at 12 months lost 1 line of CDVA. The initial study of this IOL (Venter et al., 2014) found a loss of 1 line, similar to the 3-month result in the current study. An increase in the percentage of eyes that lost 1 line was observed at 12 months; however, 19 of the 22 eyes achieved a CDVA of 0.0 logMAR or better.

This study found the predictability of the asymmetric multifocal IOL to be excellent. For the accuracy of the SE to the intended target, 86 eyes (86%) were within ± 0.50 D and 99 eyes (99%) were within ± 1.00 D of emmetropia 3 months postoperatively, which is similar to the 84.9% of eyes within ± 0.50 D and 99.1% of eyes within ± 1.00 D of emmetropia found by Venter et al., (2014) At the 12-month assessment in our study, 82 eyes (82%) were within ± 0.50 D and 98 eyes (98%) were within ± 1.00 D of emmetropia. In addition, no significant difference was found in the SE refraction between the 3-month and 12-month assessments, highlighting excellent stability after implantation of the asymmetric multifocal IOL. However, there was a statistically significant difference in both the refractive sphere and cylinder between the 2 postoperative assessments (0.10 D), which was not clinically significant.

It is well recognized that assessment of subjective perception of vision is important in fully understanding how individuals perceive their vision. Therefore, this study sought to determine subjective patient satisfaction through a QoV questionnaire (McAlinden et al., 2010). We added a new feature to our QoV questionnaire. We asked each patient to rate his or her overall QoV out of 10, with 0 being the worst and 10 the best. We found an excellent mean QoV score at the 3-month assessment, which was similar to that found 3 months postoperatively with the first asymmetric multifocal IOL positioned inferonasally in each eye (de Wit et al., 2015). However, there was a significant improvement in overall QoV at 12 months in our study ($P \leq .001$, paired t test). In addition, the incidence of patients affected by symptoms was low at both assessments. Blurred vision is one of the most common causes of dissatisfaction after multifocal IOL implantation (Rosen et al., 2016; Woodward et al., 2009; de Vries et al., 2011). Our patients said they were significantly less affected by blurred vision at the 12-month assessment than they were at the 3-month assessment ($P = .049$, Wilcoxon rank-sum test). The asymmetric multifocal IOL provided excellent visual and refractive outcomes, and there was no significant difference between the 2 postoperative assessments; however, there was a statistically significant improvement in overall QoV at the 12-month assessment. Furthermore, no patient reported a reduction in their overall QoV at the 12-month assessment when directly compared to the 3-month assessment. It seems as though neuroadaptation might potentially be involved in the reported subjective patient findings of significantly less blurred vision and a higher level of overall QoV ($8.84 \pm 1.08$) 12 months postoperatively that occurred between the 2 timepoints in this study. In many cases, spectacle independence is the motive for having multifocal IOL implantation, and our study found that the asymmetric multifocal IOL resulted in an excellent level of freedom from reading spectacles. At both postoperative assessments, the majority of patients reported never requiring reading spectacles, with a greater percentage of patients in this category 12 months postoperatively. No patients reported requiring reading spectacles quite often or always at the second postoperative assessment. A previous study that assessed an asymmetric multifocal IOL at 6 months (Muñoz et al., 2011) found that 84.4% of patients never used spectacles for reading, which is similar to the result in our study at 3 months. However, we had a higher rate of spectacle independence 12 months postoperatively, which was similar to the 12-month postoperative rate found in a study that assessed mix-and-match multifocal IOL implantation (Muñoz et al., 2012).

In conclusion, our study of the newest asymmetric multifocal IOL up to 12 months after bilateral implantation found that this refractive rotationally asymmetric IOL provided excellent vision at a range of distances with excellent predictability and stability. Although there were no statistically significant differences in the objective visual findings, there was a statistically significant difference in subjective QoV scores between the 2 postoperative assessments. At both postoperative assessments, patients reported an excellent overall QoV score; however, it seems as though neuroadaptation might have occurred between 3 months and 12 months postoperatively, resulting in significantly less blurred vision and a significantly better overall QoV score. This study provides the clinician with information on how this asymmetric multifocal IOL performs up to 12 months postoperatively and how the perception of QoV alters over this period.

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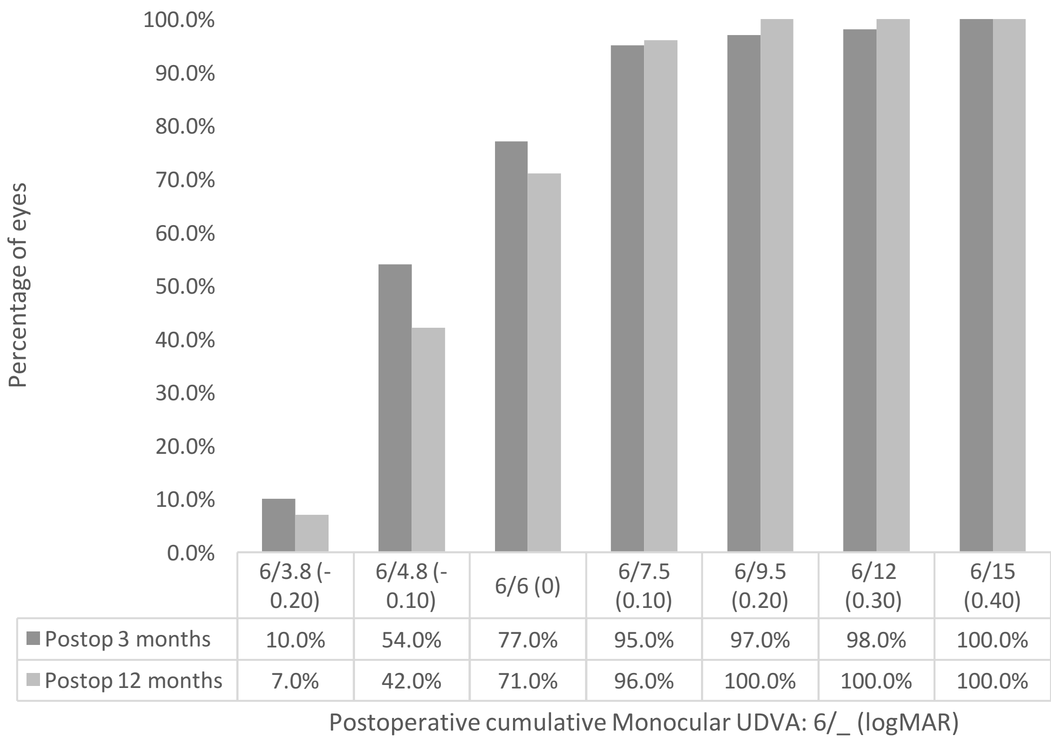
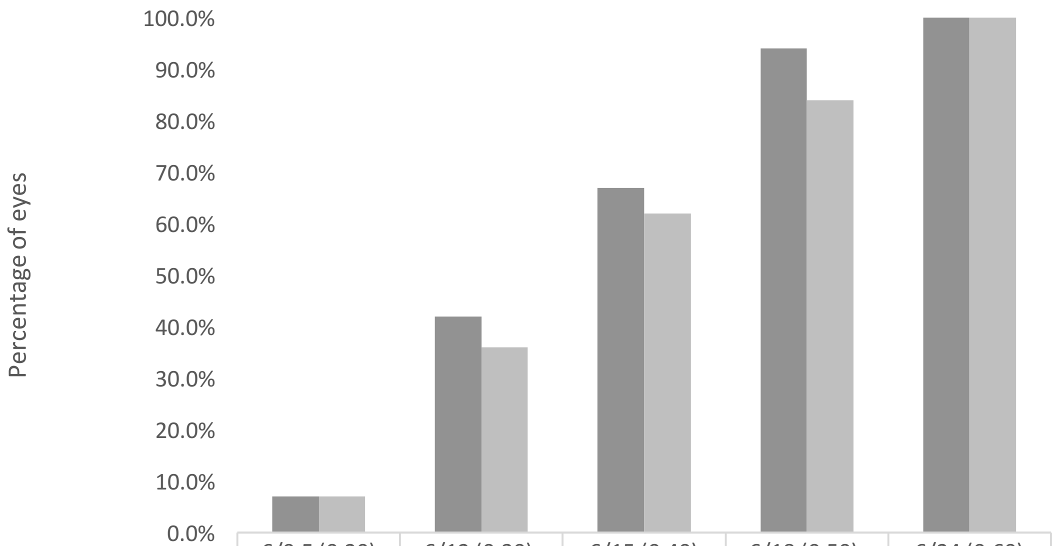
**FIGURES & TABLES**

**Figure 1 -** Cumulative monocular uncorrected (A) distance, (B) intermediate, and (C) near visual acuity 3 months and 12 months postoperatively (logMAR = logarithm of minimum angle of resolution; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA =uncorrected near visual acuity).

**A**



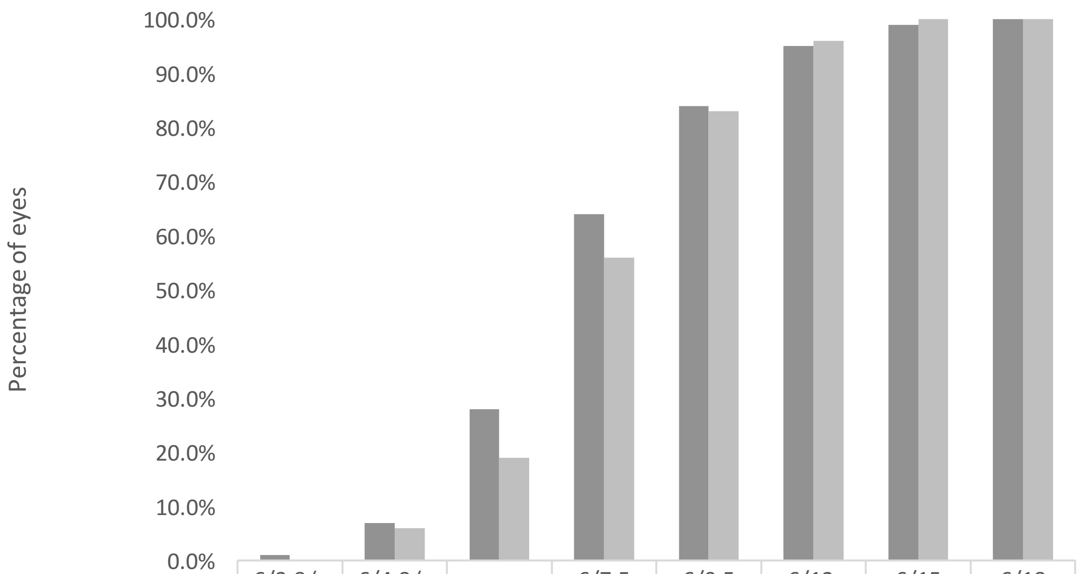
**B**




| | 6/9.5 (0.20) | 6/12 (0.30) | 6/15 (0.40) | 6/18 (0.50) | 6/24 (0.60) |
|---|---|---|---|---|---|
| Postop 3 months | 7.0% | 42.0% | 67.0% | 94.0% | 100.0% |
| Postop 12 months | 7.0% | 36.0% | 62.0% | 84.0% | 100.0% |

Postoperative cumulative Monocular UIVA: 6/_ (logMAR)

**C**




| | 6/3.8 (-0.20) | 6/4.8 (-0.10) | 6/6 (0) | 6/7.5 (0.10) | 6/9.5 (0.20) | 6/12 (0.30) | 6/15 (0.40) | 6/18 (0.60) |
|---|---|---|---|---|---|---|---|---|
| Postop 3 months | 1.0% | 7.0% | 28.0% | 64.0% | 84.0% | 95.0% | 99.0% | 100.0% |
| Postop 12 months | 0.0% | 6.0% | 19.0% | 56.0% | 83.0% | 96.0% | 100.0% | 100.0% |

Postoperative cumulative Monocular UNVA: 6/_ (logMAR)

**Figure 2 -** Changes in CDVA Snellen lines postoperatively (CDVA = corrected distance visual acuity).

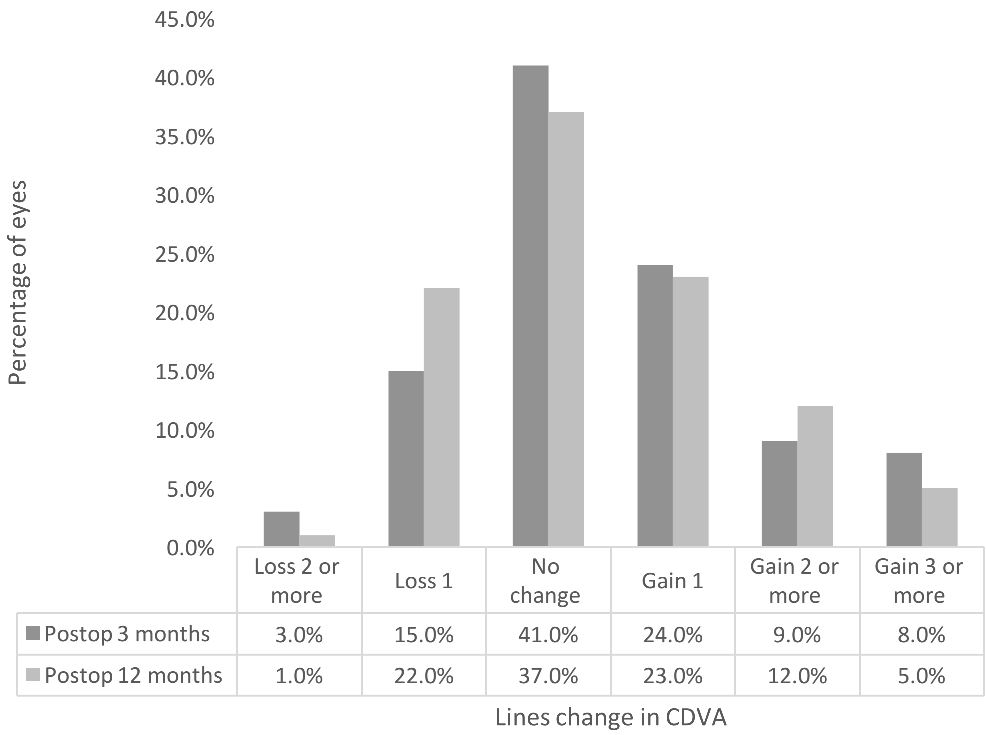


**Figure 3** – Difference between postoperative UDVA and CDVA (CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity).

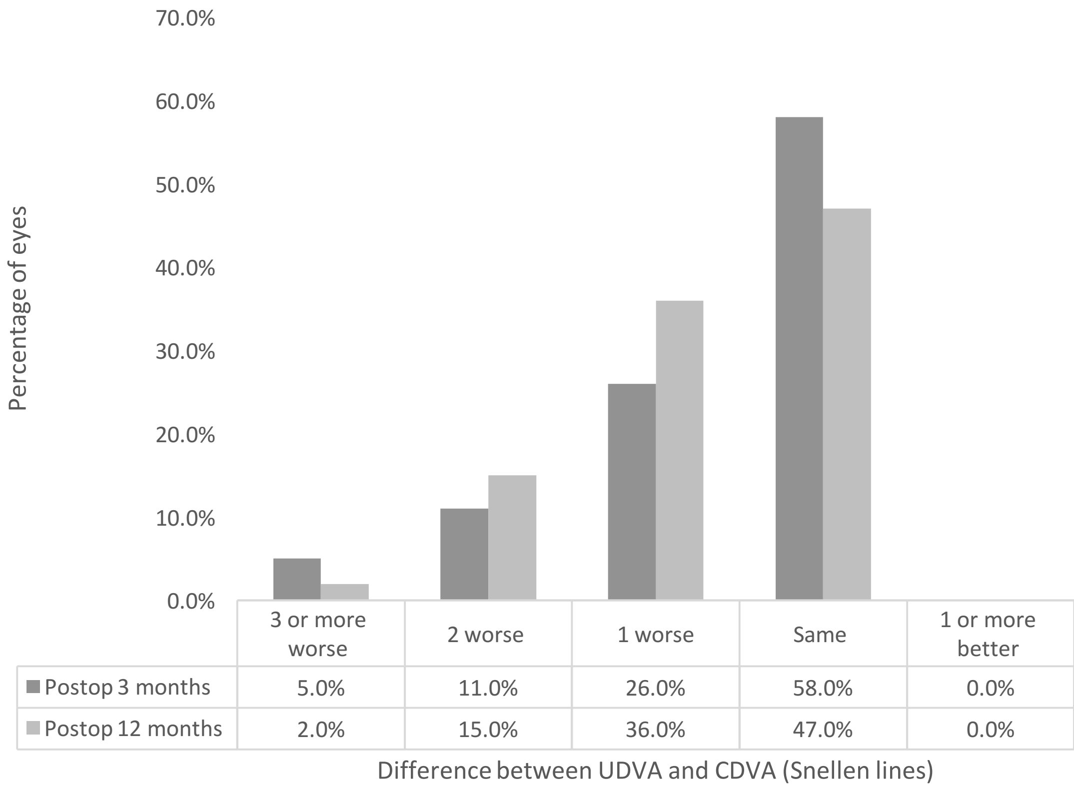
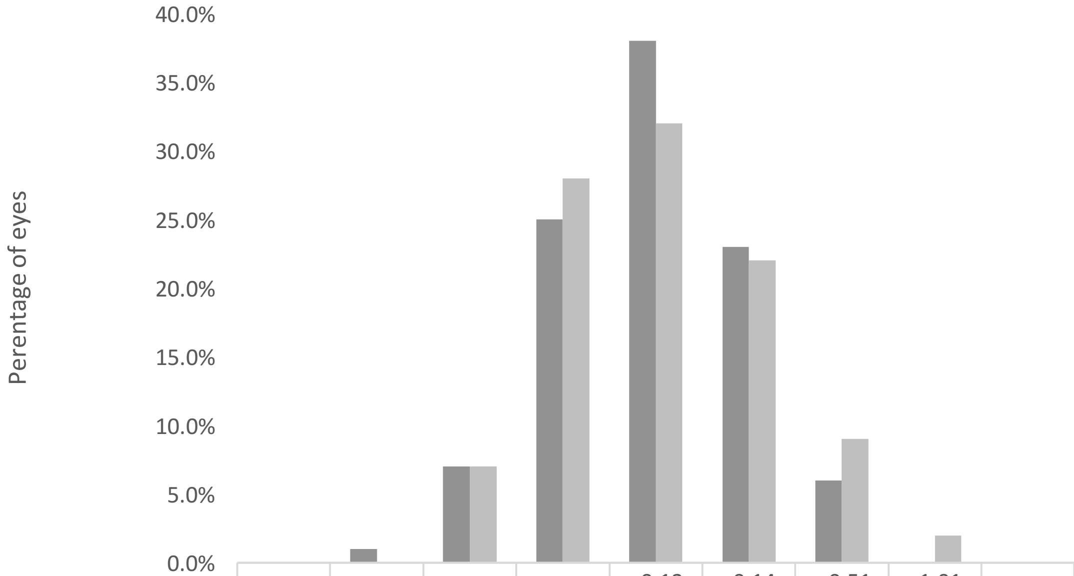


**Figure 4 -** The accuracy of the intended SE refraction at the 3-month and 12-month postoperative assessments (SE = spherical equivalent).




| | < -1.50 | -1.50 to -1.01 | -1.00 to -0.51 | -0.50 to -0.14 | -0.13 to +0.13 | +0.14 to +0.50 | +0.51 to +1.00 | +1.01 to +1.50 | > +1.50 |
|---|---|---|---|---|---|---|---|---|---|
| Postop 3 months | 0.0% | 1.0% | 7.0% | 25.0% | 38.0% | 23.0% | 6.0% | 0.0% | 0.0% |
| Postop 12 months | 0.0% | 0.0% | 7.0% | 28.0% | 32.0% | 22.0% | 9.0% | 2.0% | 0.0% |

**Figure 5** – Histogram of the postoperative refractive cylinder at the 3-month and 12-month postoperative assessments.

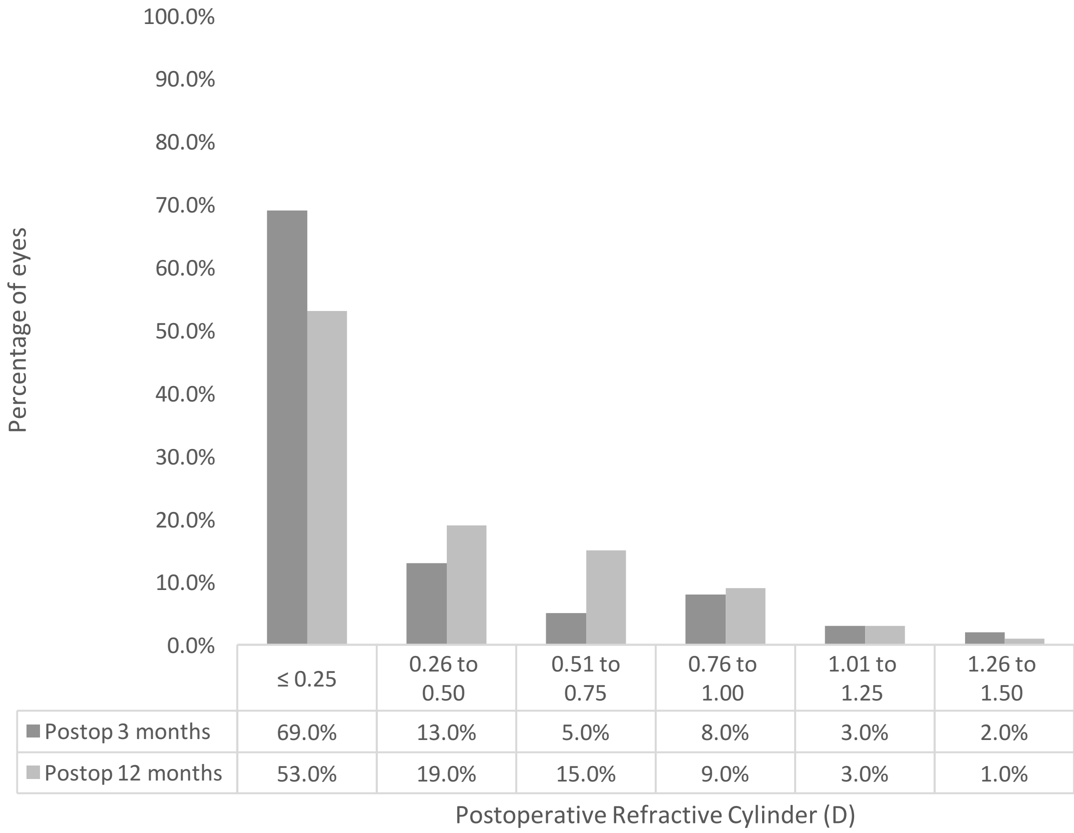


**Figure 6 -** Stability up to 12 months postoperatively plotted as the mean ± SD of the SE refraction.

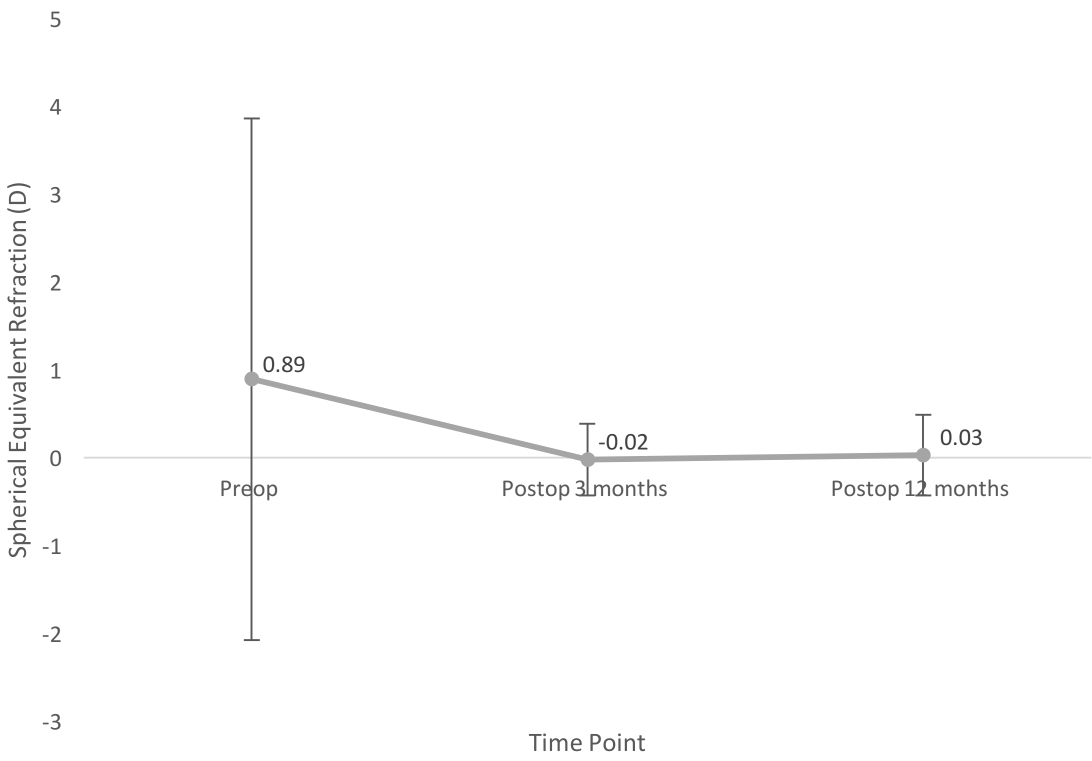
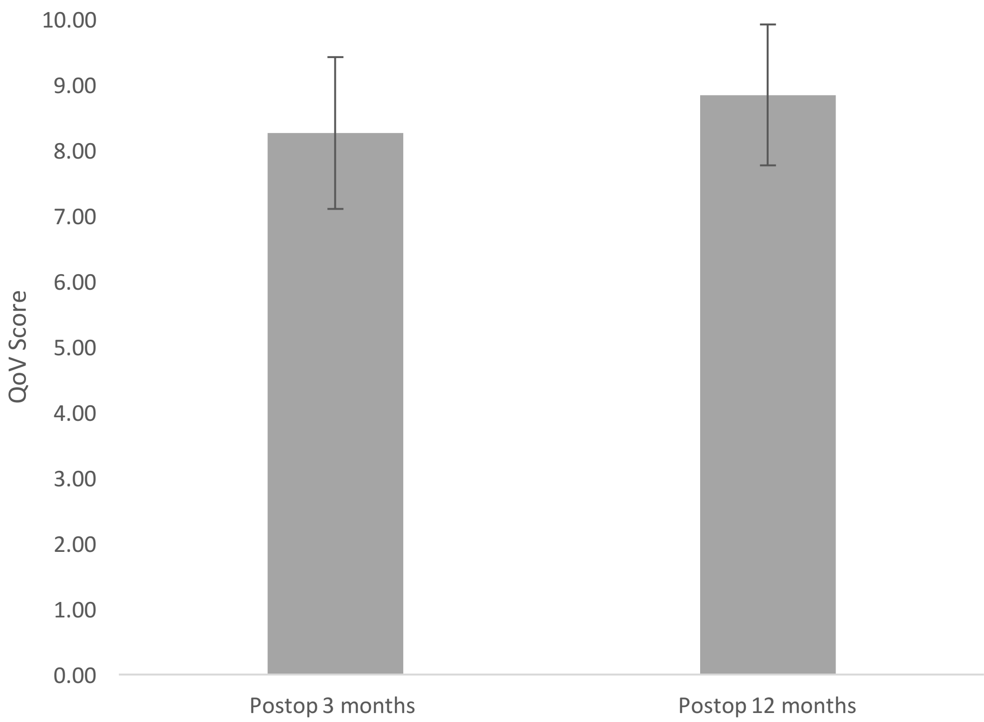


**Figure 7 – (A)** The mean overall QoV scores (0 = worst; 10 = best) for the 2 postoperative assessments (B) Box plot of the QoV responses at the 2 postoperative assessments. (QoV = quality of vision).

A



B

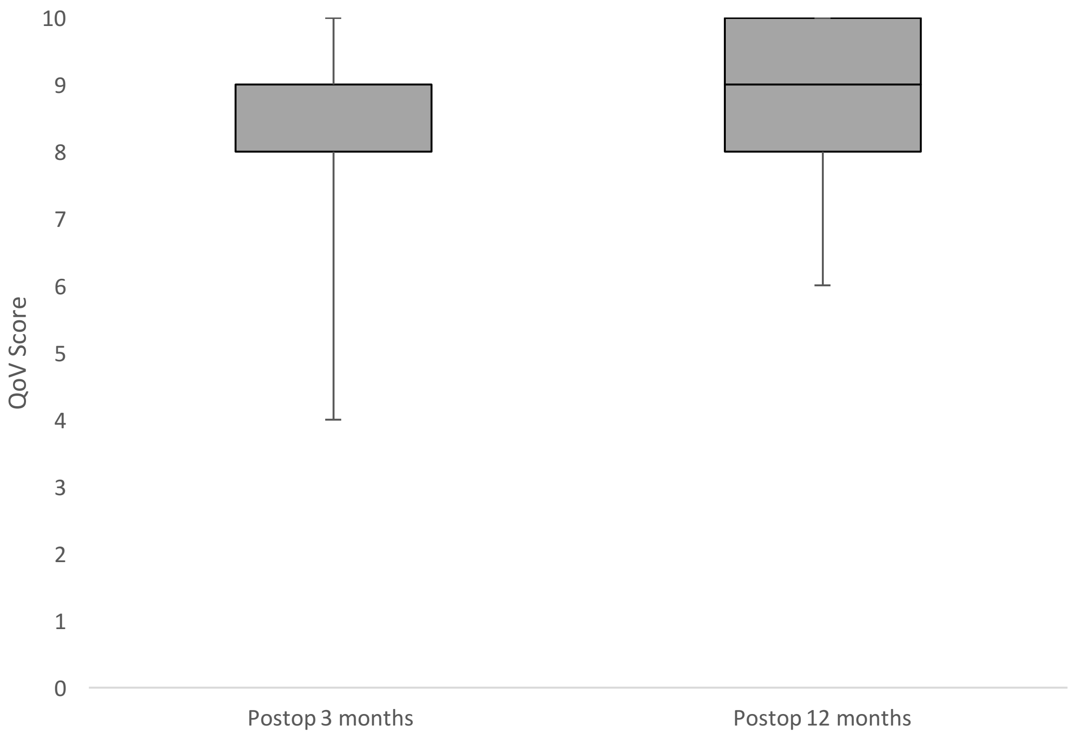
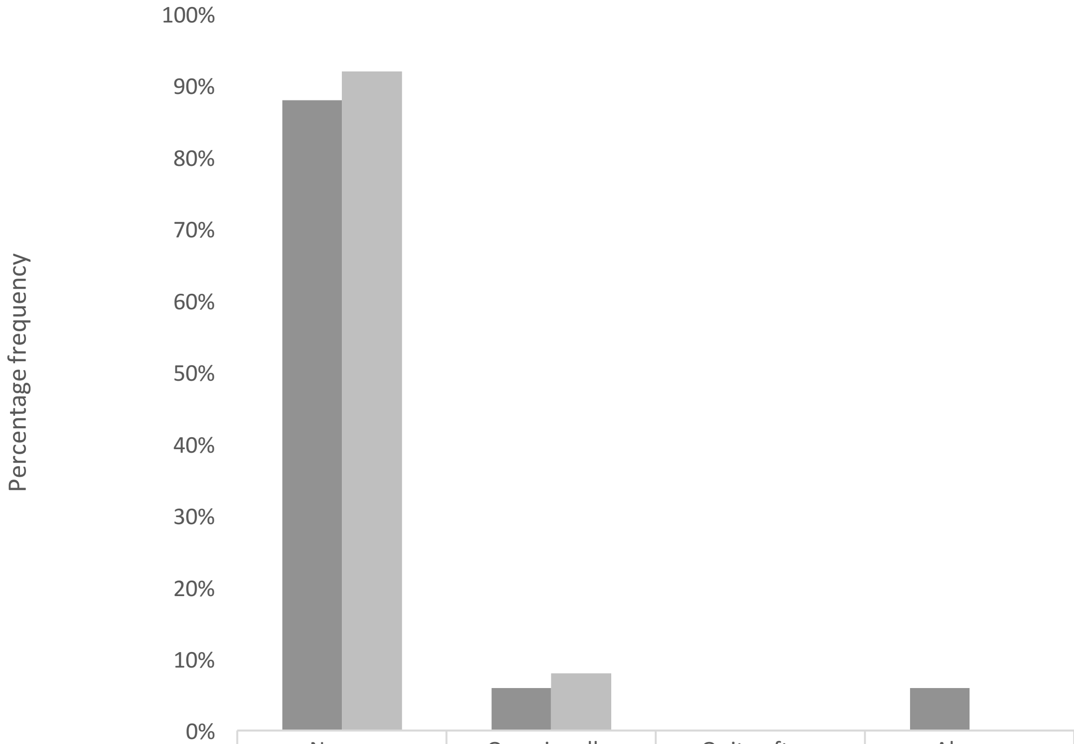


**Figure 8 -** The percentage frequency of the 3-month and 12-month postoperative responses to how often the patients wore reading spectacles.




| | Never | Occasionally | Quite often | Always |
|---|---|---|---|---|
| Postop 3 months | 88% | 6% | 0% | 6% |
| Postop 12 months | 92% | 8% | 0% | 0% |

**Table 1 -** Preoperative patient demographics.

| | |
|---|---|
| **Eyes (n)** | 100 |
| **Male, n (%)** | 13 (26) |
| **Female, n (%)** | 37 (74) |
| **Age (y)** | |
| Mean ± SD | 60.12 ± 7.75 |
| Median | 59 |
| Range | 43, 83 |
| **Sphere (D)** | |
| Mean ± SD | 1.21 ± 2.90 |
| Median | 1.50 |
| Range | -10.75, 8.75 |
| **Cylinder (D)** | |
| Mean ± SD | -0.59 ± 0.55 |
| Median | -0.50 |
| Range | -2.25, 0 |
| **LogMAR CDVA** | |
| Mean ± SD | -0.05 ± 0.12 |
| Median | -0.10 |
| Range | -0.20, 0.32 |

**Table 2 -** Comparison of 3-month and 12-month objective postoperative data after bilateral asymmetric multifocal IOL implantation.

| | **Postop 3 months** | **Postop 12 months** | **P Value** |
|---|---|---|---|
| **LogMAR UDVA** | | | |
| Mean ± SD | -0.02 ± 0.12 | -0.01 ± 0.10 | 0.393 |
| Median | -0.06 | 0 | |
| Range | -0.20, 0.42 | -0.20, 0.20 | |
| **Sphere (D)** | | | |
| Mean ± SD | 0.12 ± 0.43 | 0.22 ± 0.50 | 0.007 |
| Median | 0 | 0 | |
| Range | -0.75, 1.25 | -0.75, 1.50 | |
| **Cylinder (D)** | | | |
| Mean ± SD | -0.28 ± 0.40 | -0.38 ± 0.40 | 0.001 |
| Median | 0 | -0.25 | |
| Range | -1.50, 0 | -1.50, 0 | |
| **SE (D)** | | | |
| Mean ± SD | -0.02 ± 0.41 | 0.03 ± 0.46 | 0.132 |
| Median | 0 | 0 | |
| Range | -1.00, 1.25 | -1.00, 1.25 | |
| **LogMAR CDVA** | | | |
| Mean ± SD | -0.09 ± 0.07 | -0.09 ± 0.08 | 0.186 |
| Median | -0.10 | -0.10 | |
| Range | -0.20, 0.10 | -0.20, 0.18 | |
| **LogMAR UIVA** | | | |
| Mean ± SD | 0.39 ± 0.11 | 0.41 ± 0.12 | 0.06 |
| Median | 0.40 | 0.40 | |
| Range | 0.20, 0.60 | 0.20, 0.60 | |
| **LogMAR UNVA** | | | |
| Mean ± SD | 0.12 ± 0.13 | 0.14 ± 0.12 | 0.077 |
| Median | 0.10 | 0.10 | |
| Range | -0.20, 0.50 | -0.10, 0.40 | |
| **LogMAR DCIVA** | | | |
| Mean ± SD | 0.38 ± 0.11 | 0.39 ± 0.10 | 0.17 |
| Median | 0.30 | 0.40 | |
| Range | 0.20, 0.70 | 0.20, 0.70 | |
| **LogMAR DCNVA** | | | |
| Mean ± SD | 0.11 ± 0.13 | 0.11 ± 0.12 | 0.921 |
| Median | 0.10 | 0.10 | |
| Range | -0.10, 0.70 | -0.10, 0.40 | |

*UDVA = unaided distance visual acuity, SD = standard deviation, D = Dioptres,* SE = spherical equivalent, *CDVA = corrected distance visual acuity, UIVA = unaided intermediate visual acuity, UNVA = unaided near visual acuity, DCIVA = distance corrected intermediate visual acuity, DCNVA = distance corrected near visual acuity*

**Table 3 -** Comparison of 3-month and 12-month subjective postoperative data after bilateral asymmetric multifocal IOL implantation.*

| | **Postop 3 months** | **Postop 12 months** | **P value†** |
|---|---|---|---|
| **Glare** | 0.52 ± 0.54 | 0.54 ± 0.81 | 0.948 |
| **Halos** | 0.32 ± 0.74 | 0.20 ± 0.40 | 0.268 |
| **Starburst** | 0.48 ± 0.81 | 0.42 ± 0.73 | 0.659 |
| **Hazy** | 0.34 ± 0.72 | 0.42 ± 0.78 | 0.49 |
| **Blurred vision** | 0.56 ± 0.81 | 0.36 ± 0.75 | 0.049 |
| **Distortion** | 0.08 ± 0.34 | 0.06 ± 0.31 | 0.783 |
| **Double vision** | 0.06 ± 0.24 | 0.16 ± 0.55 | 0.197 |
| **Vision fluctuation** | 0.46 ± 0.79 | 0.32 ± 0.68 | 0.315 |
| **Depth perception difficulty** | 0.10 ± 0.36 | 0.02 ± 0.14 | 0.102 |

**Grading scale: 0 = Not at all; 1 = A little; 2 = Quite; 3 = Very*
*†Wilcoxon signed ranks test*

# 5. PAPER-IV

**Visual quality and performance comparison between 2 refractive rotationally asymmetric multifocal intraocular lenses**

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**Contributions**

Richard N. McNeely – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Eric Pazo – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Andrew Spence – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Olivier Richoz – *data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis*

M. Andrew Nesbit – *critical revision of manuscript, supervision*

Tara C.B. Moore – *critical revision of manuscript, supervision*

Jonathan E. Moore – *concept and design, data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis, supervision*

**Visual quality and performance comparison between 2 refractive rotationally asymmetric multifocal intraocular lenses**

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**ABSTRACT**

**Purpose:** To compare the 12-month postoperative quality of vision and visual performance of two different refractive rotationally asymmetric multifocal intraocular lenses (IOLs).

**Setting/Venue:** Cathedral Eye Clinic, Belfast, Northern Ireland, UK

**Design:** Retrospective comparative case series.

**Methods:** Refractive lens exchange (RLE) patients were divided into two groups. The first group comprised 90 eyes receiving a Lentis Mplus LS-312 MF30 IOL (Mplus Group) and the second group also comprised 90 eyes receiving a Lenstec SBL-3 IOL (SBL-3 Group). Refraction, uncorrected (UDVA) and best-corrected (CDVA) distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, distance-corrected intermediate (DCIVA) and near (DCNVA) visual acuities and quality of vision were evaluated preoperatively and up to 12 months postoperatively.

**Results:** Each group showed a high level of postoperative quality of vision at 12 months with no significant difference between the two groups (P = .919). There was no significant difference between the groups with mean monocular and binocular UDVA, monocular UIVA and monocular UNVA. The SBL-3 group achieved a statistically significantly better mean monocular DCNVA (P = .049), binocular UNVA (P= .011) and binocular DCNVA (P= .035). A higher percentage

of complete spectacle independence was found in the SBL-3 group.

**Conclusions:** Both refractive rotationally asymmetric multifocal IOLs provided an excellent level of quality of vision 12 months postoperatively. Both IOL models restored distance, intermediate and near visual function, however the SBL-3 IOLs provided a superior near visual performance.

## INTRODUCTION

Asymmetric multifocal intraocular lenses (IOLs) provide excellent levels of unaided visual acuity at a range of distances and a high postoperative patient satisfaction (Alió et al., 2012a; Alió et al., 2012b; Alió et al., 2013; Ramón et al., 2012; van der Linden et al., 2012), and are now widely used in cataract extraction surgery and refractive lens exchange (RLE). Currently there are two commercially available asymmetric multifocal IOLs; the Lentis Mplus (Oculentis GmbH, Berlin, Germany) and the Lenstec SBL-3 (Lenstec, Inc., Christ Church, Barbados). The Lentis Mplus was the first commercially available asymmetric multifocal IOL and several studies (Alió et al., 2012a; van der Linden et al., 2012; Venter et al., 2013) outline the visual performance and patient satisfaction following implantation with this IOL. The Lenstec SBL-3 IOL has since been introduced and is currently undergoing a trial in the USA. An initial study by Venter et al (Venter et al., 2014) outlines the performance of the SBL-3 IOL up to 3 months postoperatively.

It has previously been described that there is a period of neuroadaptation with multifocal IOLs (Alió and Pikkel, 2014) where visual symptoms appear to subside and overall patient satisfaction increases. This is in agreement with a study by McNeely et al (2017) where they assessed the SBL-3 IOL at 3 and 12 months postoperatively to determine overall patient satisfaction over this time period. The study found the overall quality of vision improved from 3 to 12 months postoperatively despite no statistically significant change in objective visual and refractive outcomes.

The aim of this study was therefore to compare the quality of vision and visual performance of both the Lentis Mplus and the Lenstec SBL-3 IOLs 12 months postoperatively. This would allow for neuroadaptation to occur to determine if there is any difference between these two available rotationally asymmetric multifocal IOLs.

**Patients and methods**

This retrospective study recruited consecutive patients who had RLE followed by implantation of rotationally asymmetric multifocal IOLs. The Mplus group received the Lentis Mplus LS-312 MF30 IOL and the SBL-3 group received the Lenstec SBL-3 IOL.

Patients were adequately informed of the risks and the possible need for further corneal laser refractive surgery. Each individual gave their informed consent for their anonymised data to be submitted for audit and publication. The exclusion criteria were any active ocular diseases.

**Patient Assessment**

Preoperatively, full ophthalmologic assessment was performed on all patients. Visual acuities were evaluated with logMAR charts (6m) and with Radner reading charts in M notation. The visual acuities evaluated were uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, and distance corrected intermediate (DCIVA) and near (DCNVA) visual acuities. The intermediate visual acuities were measured at 70 cm and the near visual acuities at 40cm (Radner reading charts). Keratometry, topography, slit-lamp examination, Goldmann tonometry, dilated funduscopy and retinal optical coherence tomography (Cirrus 4000 OCT; Carl Zeiss Meditec) were also completed. The IOL Master (Carl Zeiss Meditec AG) measured corneal curvature, anterior chamber depth, axial length for subsequent IOL calculation. The Hoffer Q formula and the SRK/T formula were utilised depending on axial length. Patients were examined at 3 months and 12 months postoperatively. Full ophthalmologic examination was performed as it was preoperatively. The position of the near segment was assessed at the postoperative visits to ensure that the near segment remained in the inferonasal position.

Patient satisfaction was assessed through a previously validated quality of vision (QoV) questionnaire (McAlinden et al., 2010) 12 months postoperatively. The questionnaire assessed the effect of certain visual phenomena and dysphotopsias with patients responding either not at all (0), a little (1), quite (2) or very (3). Additionally, patients were asked regarding the frequency of reading glasses use with the patient responding never (0), occasionally (1), quite often (2) or always (3). To gain an understanding of how the patient actually perceives their quality of vision and therefore how satisfied they are postoperatively the patient is now asked to rate their quality of vision out of 10; 0 the worst, 10 the best. Also, in order to assess functional intermediate vision the patients were also asked to report the quality of their intermediate vision.

**Intraocular Lens**

The Lentis Mplus LS-312 MF30 IOL (Figure 1) has a refractive design and is rotationally asymmetric containing an aspheric distance vision zone and a 3.00 D posterior sector shaped near vision segment. Superposition of interference or diffraction is avoided as light is reflected away from the optical axis when it hits the transition zone of the near segment. It is a foldable, biconvex, one-piece multifocal acrylic IOL with a 6 mm optic size and a 12 mm overall length.

The Lenstec SBL-3 (Figure 1) is a bi-aspheric asymmetrical refractive multifocal IOL. It has a distance section combined with a 3.00 D near vision segment in the anterior optic separated by a small wedge shaped transition zone. It is an acrylic multifocal IOL with a neutral aberration profile and has a 5.75 mm optic size and a 11 mm overall length.

**Surgical Technique**

The same experienced surgeon (J.E.M) performed standard on-axis clear corneal phacoemulsification surgery in all cases. The surgery was performed under Sub-Tenon or topical anaesthesia. An incision of 2.75 mm was placed on the steepest meridian to avoid the introduction of oblique astigmatism and to reduce postoperative corneal astigmatism. Implantation of the multifocal IOL into the capsular bag, with the vertical axis (reading segment) positioned inferiorly with slight nasal deviation, was performed following a 5.0 mm anterior capsulorrhexis with the refractive aim of emmetropia.

**Statistical Analysis**

SPSS for Windows (Statistical Package for the Social Sciences, Version 22, Chicago, Illinois, USA) and Excel (Microsoft; Redmond, Washington, USA) were utilised for the statistical analysis. The normality of the data was assessed using the

Kolmogorov-Smirnov test. Then the independent *t* test was utilised for parametric analysis and when assessing nonparametric data the Mann-Whitney U test was applied. Following the methods outlined by Goodall et al., (2009) a sample size of 36 patients was required for 80% statistical power. The standard deviation of the quality of vision was determined to be 0.90 which was motivated by some insights gained through results from previous use of the same QoV questionnaire (McNeely et al., 2016a). A 0.60 difference in quality of vision was considered to be clinically significant as determined by clinical experience.

For all statistical analysis, the level of significance was $P<0.05$.

**Results**

Demographics

This was a retrospective audit study utilising 180 eyes of consecutive 90 patients ranging in age from 46 to 74 years. The Mplus group consisted of a consecutive 45 patients implanted bilaterally with the Mplus IOL all of which fulfilled the inclusion / exclusion criteria and the SBL-3 group consisted of 45 consecutive patients implanted bilaterally with the SBL-3 IOL. The preoperative parameters are outlined in Table 1.

Overall satisfaction and spectacle independence

The Mplus group displayed a mean quality of vision score of $8.84 \pm 0.90$ and the SBL-3 group a score of $8.87 \pm 1.16$. There was no significant difference between the two groups (P= .919, independent *t* test). The percentage of responses regarding spectacle independence are displayed in Figure 2.

Both groups experienced high levels of functional intermediate visual acuity with 36 out of 45 patients (80%) reporting to have clear intermediate vision and 43 patients (95.6%) reporting to experience either clear intermediate vision or a slight problem with their intermediate vision in the Mplus Group. In the SBL-3 group 38 out of 45 patients (84.4%) reported that their intermediate vision was clear and 42 patients (93.3%) reported to have clear or experience only a slight problem with their intermediate vision.

Visual disturbances and photopic phenomena

Table 2 outlines the visual disturbances and photopic phenomena experienced by the 2 groups 12 months postoperatively, where there was no significant difference between the groups with any of the parameters.

Visual acuity and refraction

Table 3 shows the visual outcomes of the 2 groups 12 months postoperatively. The SBL-3 group displayed significantly better monocular DCNVA, binocular UNVA and binocular DCNVA than the Mplus group. Figure 3 shows the cumulative monocular UDVA, UIVA, and UNVA for each group, and Figure 4 shows the cumulative binocular visual outcomes 12 months postoperatively. The safety is plotted in Figure 5 and Figure 6 displays the efficacy of the two groups. The accuracy of the attempted spherical equivalent is displayed in Figure 7 and the magnitude of the postoperative refractive cylinder in Figure 8.

There was no significant difference between the two groups with the 12-month postoperative refractive sphere, however, there was a statistically significant difference in the postoperative refractive cylinder. The postoperative refractive cylinder in the Mplus group was -0.13 ± 0.24 D and -0.38 ± 0.40 D in the SBL-3 group (P= <.001, independent *t* test). The postoperative spherical equivalent was 0.02 ± 0.38 D in the Mplus group and 0 ± 0.45 D in the SBL-3 group with no statistically significant difference between the groups.

Complications

Posterior capsular opacification was present in 13.3% (12 out of 90 eyes) in both the Mplus and SBL-3 group. This presented before the 12-month postoperative assessment and YAG capsulotomy was performed prior to this final assessment. No other adverse events occurred, and no IOL rotation was noted.

## Discussion

To our knowledge this is the first study to compare the objective and subjective outcomes of the two commercially available rotationally asymmetric multifocal IOLs. Various studies have outlined the outcomes achieved by both the Mplus (Alió et al., 2012a; Ramón et al., 2012; Alió et al., 2011a) and SBL-3 IOLs (Venter et al., 2014), however no direct comparison has been performed. Therefore, the purpose of this study was to determine if there was any significant difference in subjective and objective outcomes between the two commercially available rotationally asymmetric multifocal IOLs. Neuroadaptation occurs following multifocal IOL implantation (Alió and Pikkel, 2014), therefore this study sought to compare the Mplus and SBL-3 IOLs 12 months after implantation to allow for neuroadaptation. A study by McNeely et al., (2016a) found that bilateral implantation of asymmetric multifocal IOLs with a combination of superotemporal placement of the near segment in the dominant eye and inferonasal placement of the near segment in the fellow eye displayed enhanced quality of vision when compared to bilateral inferonasal placement. Another study (Song et al., 2016) found that the placement of the near segment had no significant effect on visual performance, however the numbers in this study are too small. Due to the impact of near segment position with asymmetric multifocal IOLs the near segment position was assessed and confirmed to be inferonasally to ensure this did not affect the outcomes of this study.

In this study both IOL models achieved high levels of quality of vision 12 months postoperatively. There was no significant difference between the two groups with the overall scores. the Mplus group achieved a mean score of 8.84 ± 0.90 and the SBL-3 group a score of 8.87 ± 1.16. This is similar to that found by Muñoz et al., (2011) where they found the Lentis Mplus IOL to have an overall satisfaction score of 8.80 ± 0.88 (0 (least satisfied) to 10 (most satisfied)) 6 months postoperatively. An initial study (Venter et al., 2014) of the SBL-3 IOL found that 75.5% of patients were very satisfied and 18.9% were satisfied with the procedure 3 months following bilateral implantation. Additionally, there was no statistically significant difference in individual symptom responses between the two groups 12 months postoperatively (Table 2). The patients were also asked how often they required reading glasses. Figure 2 shows the percentage frequency of patients requiring reading glasses. the SBL-3 group displayed a higher percentage of patients reporting to never need reading glasses, with 42 out of 45 patients (93.3%) compared to 37 out of 45 patients (82.2%) in the Mplus group.

Table 3 outlines the objective visual outcomes of the two groups 12 months postoperatively.

The UDVA achieved in the Mplus group was -0.03 ± 0.09 logMAR which is similar to that found in previous studies (Venter et al., 2013; Muñoz et al., 2011) assessing bilateral Mplus IOLs up to 6 months postoperatively. In an initial study (Venter et al., 2014) of bilateral SBL-3 IOL implantation the 3-month postoperative monocular UDVA was -0.03 ± 0.09 logMAR which is similar to that found in this current study. There was no significant difference between the two groups with binocular UDVA and 40 patients (88.9%) in each group achieved a binocular UDVA of 6/6 (0.0 logMAR) or better, which is superior to that found in an extensive study by Venter et al., (2013). There was no significant difference between the two groups with monocular or binocular UIVA and DCIVA. The level of UIVA and DCIVA achieved is inferior to that found in previous studies (Muñoz et al., 2011; Alió et al., 2011b). However, McAlinden and Moore, (2011) reported a mean intermediate vision of M0.89 (approximately 0.35 logMAR) following implantation of a +1.50 D addition in the dominant eye and a +3.00 D addition in the fellow eye, which is similar to that found in this current study and the +1.50 D in the dominant eye was utilised to optimise intermediate visual acuity. In order to understand the level of functional intermediate visual acuity patients were asked to report if their intermediate vision is clear or if they find it problematic. Both groups experienced high levels of functional intermediate visual acuity with 43 patients (95.6%) reporting either clear intermediate vision or a slight problem with their intermediate vision in the Mplus group compared to 42 patients (93.3%) in the SBL-

3 group. Additionally, both groups achieved monocular UNVA similar to that found in an extensive study by Venter et al., (2013) with no statistically significant difference between the groups. However, the binocular UNVA was statistically significantly better in the SBL-3 group and was slightly better than that found in the initial SBL-3 study (Venter et al., 2014). The SBL-3 group also achieved a statistically significantly better monocular DCNVA than the Mplus group. The DCNVA achieved by the SBL-3 group in this study was similar to that found in a previous SBL-3 IOL study (Venter et al. 2014), where they found a binocular DCNVA of 0.08 ± 0.09 logMAR. The Mplus group displayed a DCNVA of 0.16 ± 0.11 logMAR which is similar to that found by Rosa et al., (2013) 3 months postoperatively, however a study (Muñoz et al., 2011) reporting on the 6-month outcomes following bilateral implantation of Mplus IOLs report a DCNVA of 0.07 ± 0.07 logMAR. Likewise, the binocular DCNVA was better following bilateral SBL-3 IOL implantation and was superior to that found in the initial SBL-3 study (Venter et al., 2014). This would appear to suggest that the SBL-3 IOL has a superior near visual performance than the Mplus IOL, highlighted by a better near performance when lower order aberrations are corrected when assessing DCNVA, and with a superior binocular UNVA. The reason for this apparent superiority in near vision of the SBL-3 IOL is unknown, but the unique features of the IOL such as a larger surface area of near addition without loss of the central aspect, and the addition reaching almost completely to the edge of the optic along with the equiconic bi-aspheric nature of the platform may contribute to its enhanced efficacy. This may suggest that when considering multifocal IOL implantation with an individual who has high near visual demands bilateral SBL-3 IOL implantation would be the more suitable IOL to implant. This is supported by a higher percentage

of patients reporting to never require reading glasses when questioned specifically about spectacle independence.

Both IOL models display an excellent level of safety and efficacy 12 months postoperatively as outlined in Figure 5 & 6. The accuracy to the intended spherical equivalent is shown in Figure 7 and the postoperative refractive cylinder in Figure 8. The intended spherical results were superior to that found in a large population study (Aristodemou et al., 2011). There was no significant difference between the two groups in mean spherical equivalent at 12 months, with 0.02 ± 0.38 D in the Mplus group and 0 ± 0.45 D in the SBL-3 group, which is a very good outcome and similar to a previous study (Venter et al., 2013) looking at Mplus IOLs up to 6 months postoperatively. There was a significant difference in refractive cylinder however this was not clinically relevant. The difference in postoperative refractive cylinder was deemed not to be clinically significantly different because there was only a difference of 0.25 D between the two groups, and it has been found previously by McNeely et al., (2016b) that an increasing magnitude of postoperative refractive cylinder does not have a significant impact on quality of vision, UIVA and UNVA following implantation of an asymmetric multifocal IOL.

In conclusion, to our knowledge, this is the first study to evaluate the Mplus IOL or SBL-3 IOL up to 12 months postoperatively and the first study to directly compare the two IOL models. Both IOLs provided excellent postoperative outcomes up to 12 months postoperatively. There was no significant difference between the two IOL models in overall patient satisfaction and visual phenomena or dysphotopsias. Unaided visual acuity was excellent with both IOL models, although the SBL-3 IOL appeared to provide better near visual performance and implantation of this IOL may prove to be a more suitable choice in patients with high near visual demands.

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**FIGURES & TABLES**

**Figure 1** Top: The Mplus multifocal IOL. Bottom: The SBL-3 multifcoal IOL.

**Figure 2 -** Percentage frequency of patients' responses to how often they wore reading glasses (45 patients in each group).

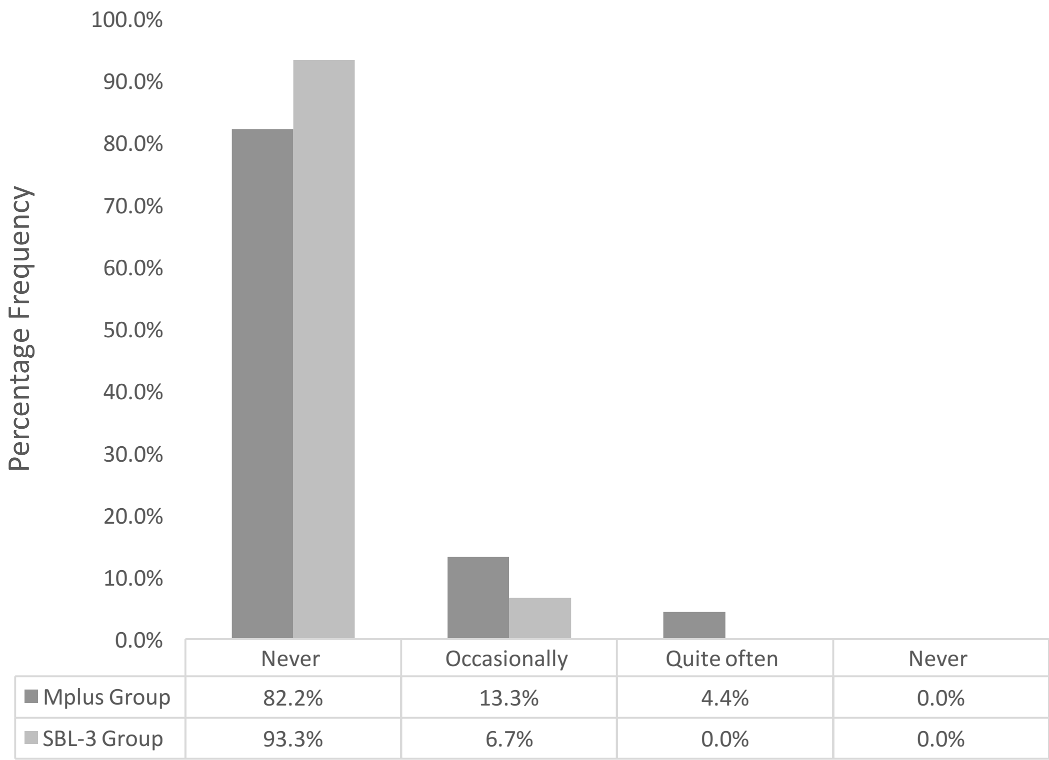
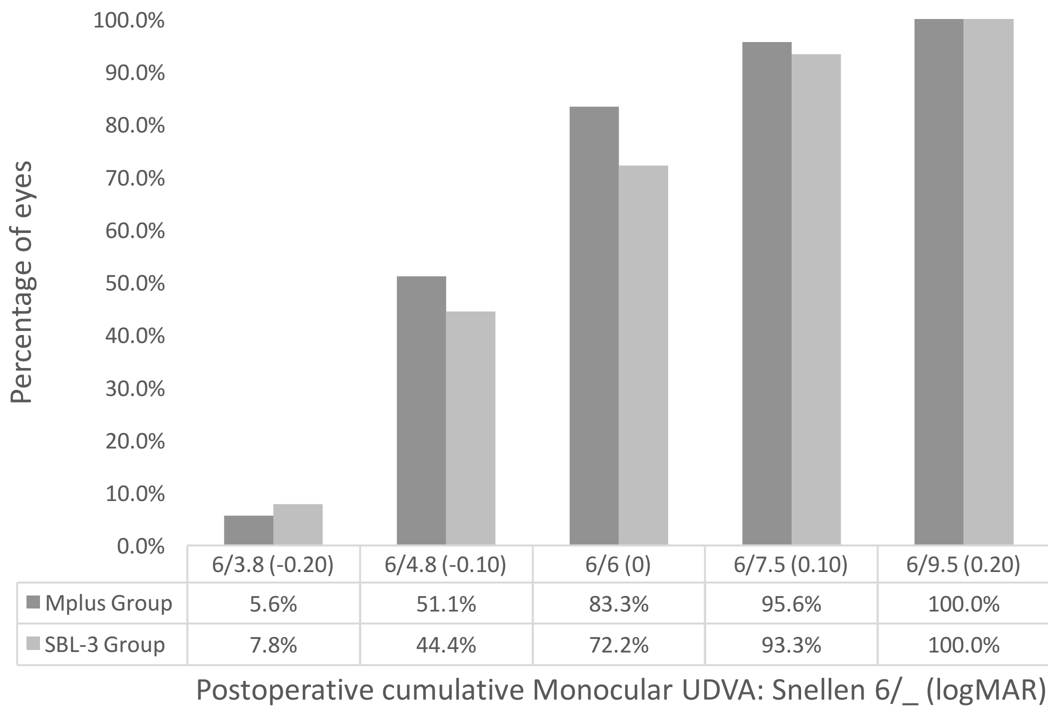
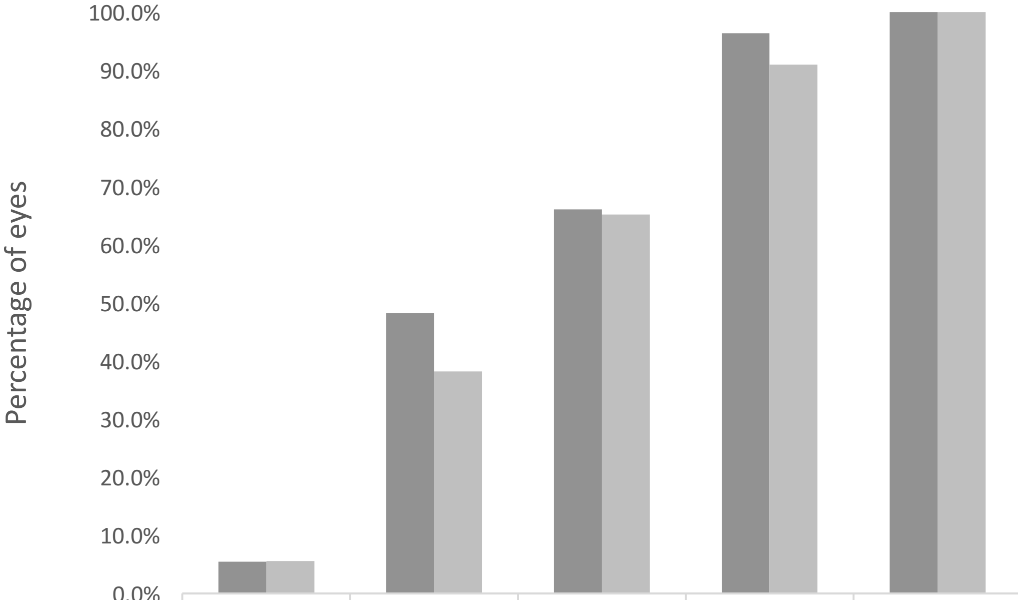


**Figure 3 -** Cumulative monocular uncorrected distance, intermediate, and near visual acuities 12 months postoperatively in the 2 groups (90 eyes in each group) (UDVA = uncorrected distance visual acuity; UIVA = intermediate distance visual acuity; UNVA = intermediate near visual acuity)

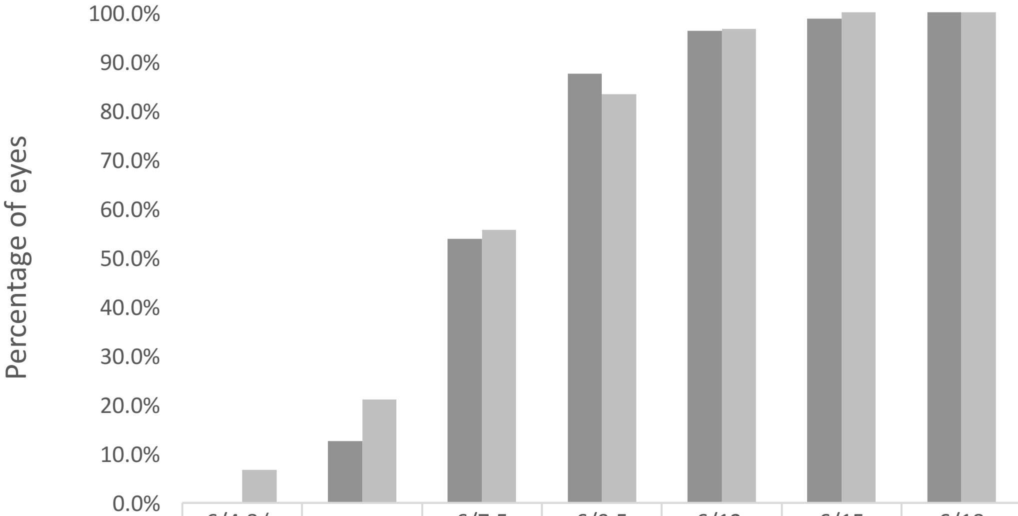



| | 6/3.8 (-0.20) | 6/4.8 (-0.10) | 6/6 (0) | 6/7.5 (0.10) | 6/9.5 (0.20) |
|---|---|---|---|---|---|
| Mplus Group | 5.6% | 51.1% | 83.3% | 95.6% | 100.0% |
| SBL-3 Group | 7.8% | 44.4% | 72.2% | 93.3% | 100.0% |




| | 6/9.5 (0.20) | 6/12 (0.30) | 6/15 (0.40) | 6/18 (0.50) | 6/24 (0.60) |
|---|---|---|---|---|---|
| Mplus Group | 5.4% | 48.2% | 66.1% | 96.4% | 100.0% |
| SBL-3 Group | 5.6% | 38.2% | 65.2% | 91.0% | 100.0% |

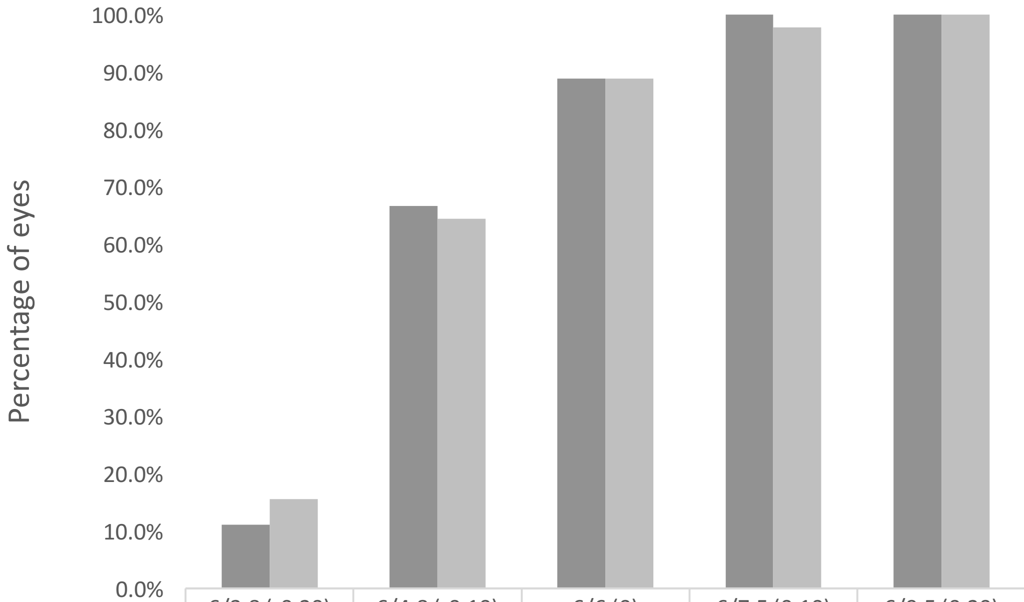
Postoperative cumulative Monocular UIVA: Snellen 6/_ (logMAR)




| | 6/4.8 (-0.10) | 6/6 (0) | 6/7.5 (0.10) | 6/9.5 (0.20) | 6/12 (0.30) | 6/15 (0.40) | 6/18 (0.50) |
|---|---|---|---|---|---|---|---|
| Mplus Group | 0.0% | 12.5% | 53.8% | 87.5% | 96.3% | 98.8% | 100.0% |
| SBL-3 Group | 6.7% | 21.1% | 55.6% | 83.3% | 96.7% | 100.0% | 100.0% |

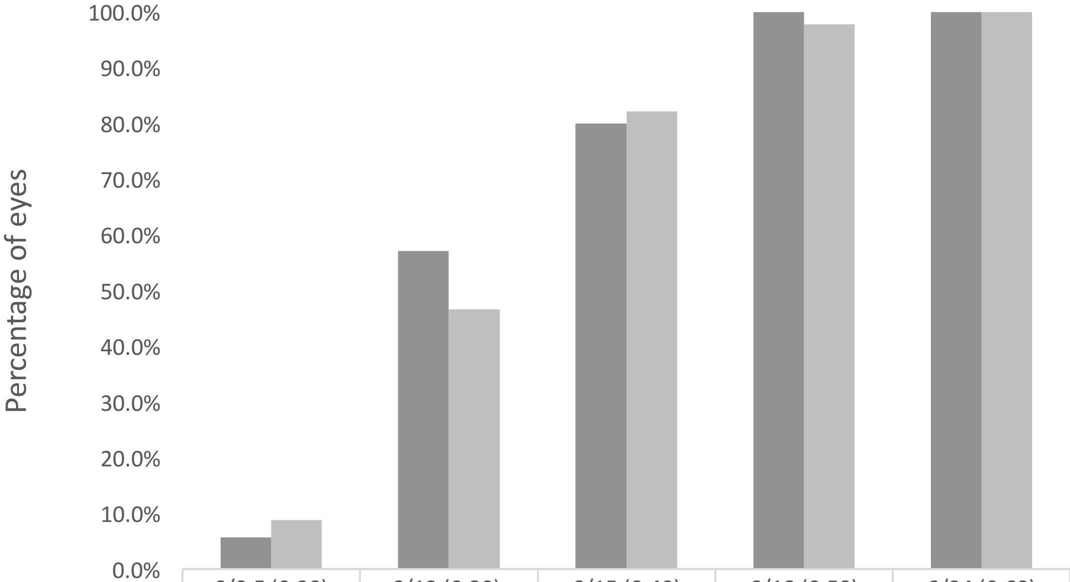
Postoperative cumulative Monocular UNVA: Snellen 6/_ (logMAR)

**Figure 4 -** Cumulative binocular uncorrected distance, intermediate, and near visual acuities 12 months postoperatively in the 2 groups (90 eyes in each group) (UDVA = uncorrected distance visual acuity; UIVA = intermediate distance visual acuity; UNVA = intermediate near visual acuity).



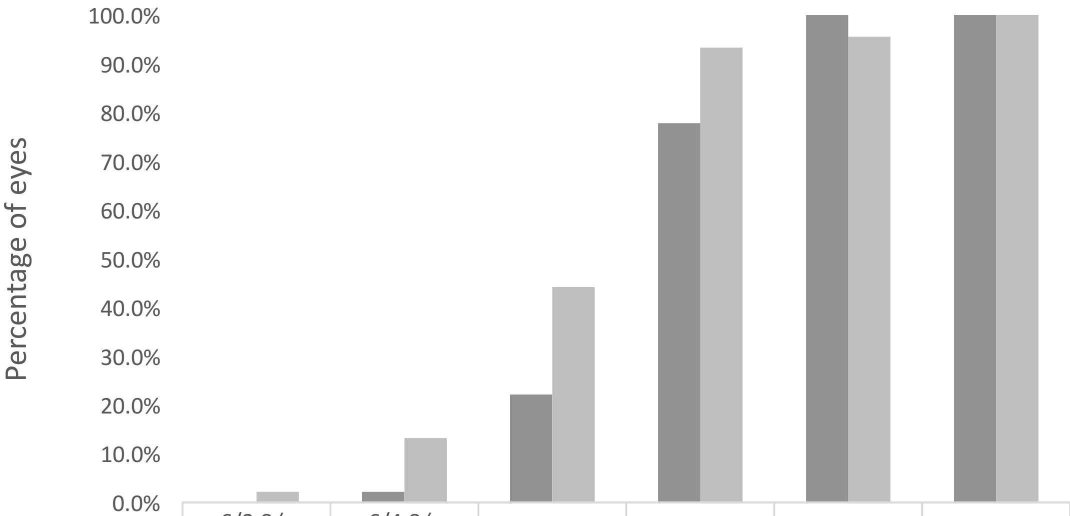

| | 6/3.8 (-0.20) | 6/4.8 (-0.10) | 6/6 (0) | 6/7.5 (0.10) | 6/9.5 (0.20) |
|---|---|---|---|---|---|
| Mplus Group | 11.1% | 66.7% | 88.9% | 100.0% | 100.0% |
| SBL-3 Group | 15.6% | 64.4% | 88.9% | 97.8% | 100.0% |

Postoperative cumulative Binocular UDVA: Snellen 6/_ (logMAR)




| | 6/9.5 (0.20) | 6/12 (0.30) | 6/15 (0.40) | 6/18 (0.50) | 6/24 (0.60) |
|---|---|---|---|---|---|
| Mplus Group | 5.7% | 57.1% | 80.0% | 100.0% | 100.0% |
| SBL-3 Group | 8.9% | 46.7% | 82.2% | 97.8% | 100.0% |

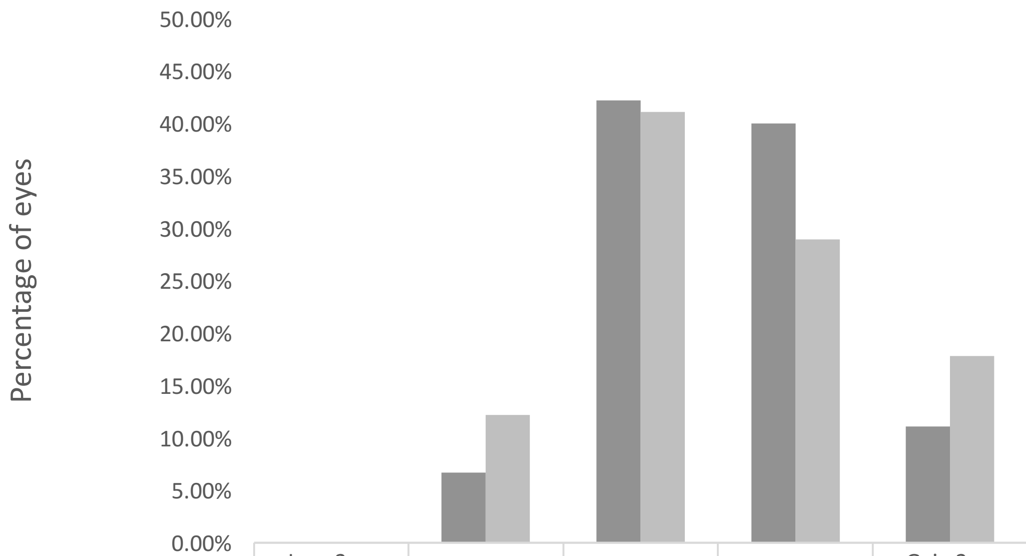
Postoperative cumulative Binocular UIVA: Snellen 6/_ (logMAR)




| | 6/3.8 (-0.20) | 6/4.8 (-0.10) | 6/6 (0) | 6/7.5 (0.10) | 6/9.5 (0.20) | 6/12 (0.30) |
|---|---|---|---|---|---|---|
| Mplus Group | 0.0% | 2.2% | 22.2% | 77.8% | 100.0% | 100.0% |
| SBL-3 Group | 2.2% | 13.3% | 44.2% | 93.3% | 95.6% | 100.0% |

Postoperative cumulative Binocular UNVA: Snellen 6/_ (logMAR)

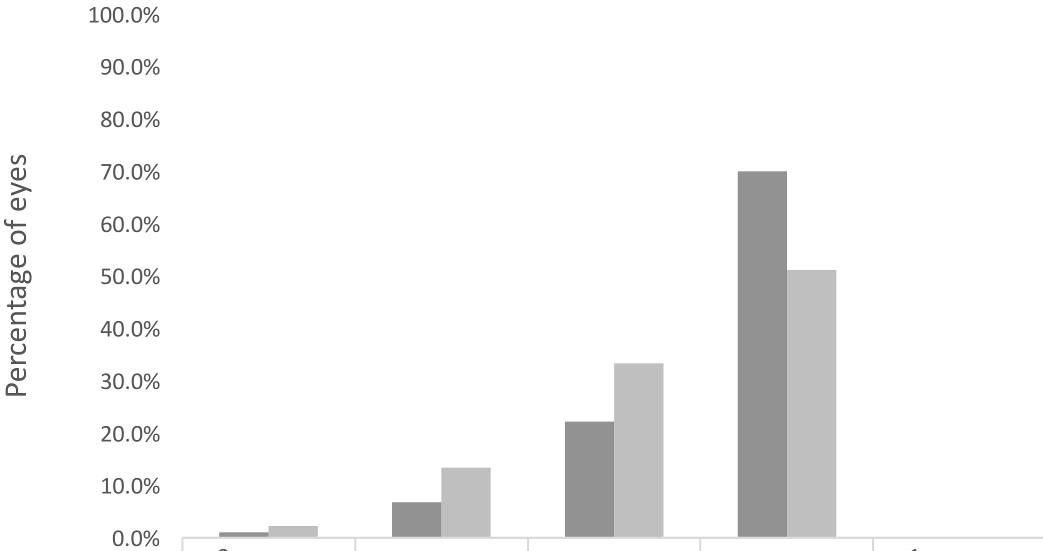
**Figure 5 -** Safety comparison of 12-month postoperative monocular CDVA 12 months postoperatively in the 2 groups (90 eyes in each group) (CDVA = corrected distance visual acuity).




| | Loss 2 or more | Loss 1 | No Change | Gain 1 | Gain 2 or more |
|---|---|---|---|---|---|
| Group A (n=90 eyes) | 0.0% | 6.7% | 42.2% | 40.0% | 11.1% |
| Group B (n=90 eyes) | 0.0% | 12.2% | 41.1% | 28.9% | 17.8% |

Lines change in CDVA

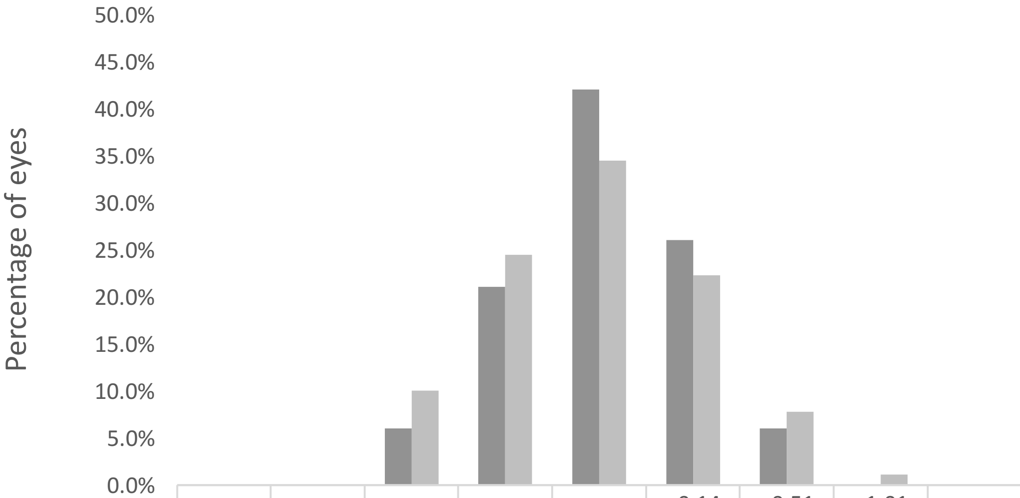
**Figure 6 –** Efficacy histogram of lines difference between postoperative UDVA and CDVA in the 2 groups (90 eyes in each group) (UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity).




| | 3 or more wirse | 2 worse | 1 worse | Same | 1 or more better |
|---|---|---|---|---|---|
| Mplus Group | 1.0% | 6.7% | 22.2% | 70.0% | 0.0% |
| SBL-3 Group | 2.2% | 13.3% | 33.3% | 51.1% | 0.0% |

Difference in UDVA and CDVA (Snellen lines)

**Figure 7 -** Accuracy to the intended SE refraction at the 12-month postoperative assessment in the 2 groups (90 eyes in each group). (SE = spherical equivalent).




| | <-1.50 | -1.50 to -1.01 | -1.00 to -0.51 | -0.50 to -0.14 | -0.13 to +0.13 | +0.14 to +0.50 | +0.51 to +1.00 | +1.01 to +1.50 | > +1.50 |
|---|---|---|---|---|---|---|---|---|---|
| Mplus Group | 0% | 0% | 6% | 21% | 42% | 26% | 6% | 0% | 0% |
| SBL-3 Group | 0% | 0% | 10% | 24% | 34% | 22% | 8% | 1% | 0% |

Postoperative Spherical Equivalent Refraction (D)

**Figure 8 –** Histogram of postoperative refractive cylinder in the 2 groups (90 eyes in each group).

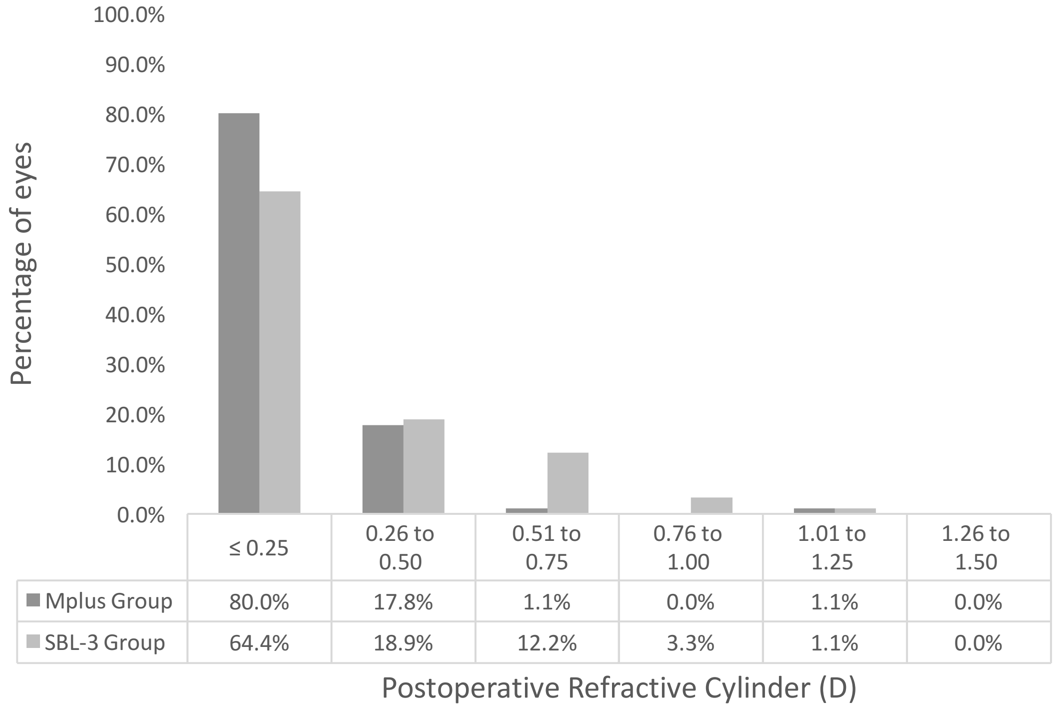


**Table 1** - Preoperative patient demographics.

| | **Mplus Group** | **SBL-3 Group** | **P value** |
|---|---|---|---|
| **Eyes (n)** | 90 | 90 | |
| **Male, n (%)** | 22 (49) | 11 (24) | |
| **Female, n (%)** | 23 (51) | 34 (76) | |
| **Age (y)** | | | |
| Mean ± SD | 63.03 ± 6.78 | 59.82 ± 6.86 | .034 |
| Median | 62 | 59 | |
| Range | 46, 74 | 47, 73 | |
| **Sphere (D)** | | | |
| Mean ± SD | 0.47 ± 4.36 | 1.33 ± 2.51 | .118 |
| Median | 1.75 | 1.50 | |
| Range | -16.50, 6.00 | -5.50, 8.75 | |
| **Cylinder (D)** | | | |
| Mean ± SD | -0.68 ± 0.55 | -0.59 ± 0.53 | .252 |
| Median | -0.50 | -0.50 | |
| Range | -2.25, 0 | -2.25, 0 | |
| **LogMAR CDVA** | | | |
| Mean ± SD | -0.04 ± 0.09 | -0.05 ± 0.11 | .351 |
| Median | -0.02 | -0.1 | |
| Range | -0.20, 0.30 | -0.20, 0.32 | |

*SD = standard deviation, D = Dioptres, CDVA = corrected distance visual acuity*

**Table 2** - Between-group comparison of 12-month postoperative subjective data.

| | **Mplus Group** | **SBL-3 Group** | **P value** |
|---|---|---|---|
| **Glare** | 0.52 ± 0.54 | 0.54 ± 0.81 | 0.745 |
| **Halos** | 0.32 ± 0.74 | 0.20 ± 0.40 | 0.138 |
| **Starburst** | 0.48 ± 0.81 | 0.42 ± 0.73 | 0.85 |
| **Hazy** | 0.34 ± 0.72 | 0.42 ± 0.78 | 0.536 |
| **Blurred vision** | 0.56 ± 0.81 | 0.36 ± 0.75 | 0.945 |
| **Distortion** | 0.08 ± 0.34 | 0.06 ± 0.31 | 0.326 |
| **Double vision** | 0.06 ± 0.24 | 0.16 ± 0.55 | 0.13 |
| **Vision fluctuation** | 0.46 ± 0.79 | 0.32 ± 0.68 | 0.439 |
| **Depth perception difficulty** | 0.10 ± 0.36 | 0.02 ± 0.14 | 0.077 |
| *Grading scale: 0 = Not at all; 1 = A little; 2 = Quite; 3 = Very* | | | |

**Table 3** - Between-group comparison of 12-month postoperative monocular and binocular visual outcomes.

| | ***Monocular*** | | | ***Binocular*** | | |
|---|---|---|---|---|---|---|
| | **Mplus Group** | **SBL-3 Group** | ***P* Value** | **Mplus Group** | **SBL-3 Group** | ***P* Value** |
| **LogMAR UDVA** | | | | | | |
| Mean ± SD | -0.03± 0.09 | -0.01 ± 0.10 | 0.217 | -0.07 ± 0.07 | -0.06 ± 0.09 | 0.629 |
| Range | -0.20, 0.24 | -0.20, 0.20 | | -0.20, 0.10 | -0.20, 0.20 | |
| **LogMAR CDVA** | | | | | | |
| Mean ± SD | -0.07 ± 0.07 | -0.08 ± 0.09 | 0.400 | -0.09 ± 0.06 | -0.11 ± 0.07 | 0.087 |
| Range | -0.20, 0.10 | -0.20, 0.20 | | 0, 0.20 | -0.20, 0.04 | |
| **LogMAR UIVA** | | | | | | |
| Mean ± SD | 0.39 ± 0.10 | 0.40 ± 0.11 | 0.55 | 0.36 ± 0.09 | 0.36 ± 0.09 | .723 |
| Range | 0.20, 0.60 | 0.20, 0.60 | | 0.20, 0.50 | 0.20, 0.60 | |
| **LogMAR UNVA** | | | | | | |
| Mean ± SD | 0.15 ± 0.10 | 0.14 ± 0.12 | 0.411 | 0.10 ± 0.07 | 0.05 ± 0.10 | .011 |
| Range | 0, 0.50 | -0.10, 0.40 | | -0.10, 0.20 | -0.20, 0.30 | |
| **LogMAR DCIVA** | | | | | | |
| Mean ± SD | 0.39 ± 0.10 | 0.36 ± 0.16 | 0.179 | 0.34 ± 0.11 | 0.35 ± 0.11 | .633 |
| Range | 0.20, 0.60 | 0, 0.70 | | 0, 0.50 | 0, 0.50 | |
| **LogMAR DCNVA** | | | | | | |
| Mean ± SD | 0.16 ± 0.11 | 0.12 ± 0.12 | 0.049 | 0.10 ± 0.07 | 0.06 ± 0.09 | .035 |
| Range | 0, 0.50 | -0.10, 0.50 | | 0, 0.20 | -0.10, 0.30 | |

*UDVA = unaided distance visual acuity, SD = standard deviation, CDVA = corrected distance visual acuity, UIVA = unaided intermediate visual acuity, UNVA = unaided near visual acuity, DCIVA = distance corrected intermediate visual acuity, DCNVA = distance corrected near visual acuity*

# 6. PAPER-V

**Threshold limit of postoperative astigmatism for patient satisfaction after refractive lens exchange and multifocal intraocular lens implantation**

Richard N. McNeely, Eric Pazo, Zack Millar, Olivier Richoz, M. Andrew Nesbit, Tara C.B. Moore, Jonathan E. Moore.

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## Contributions

Richard N. McNeely – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Eric Pazo – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Zack Millar – *critical revision of manuscript*

Olivier Richoz – *data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis*

M. Andrew Nesbit – *critical revision of manuscript, supervision*

Tara C.B. Moore – *critical revision of manuscript, supervision*

Jonathan E. Moore – *concept and design, data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis, supervision*

**Threshold limit of postoperative astigmatism for patient satisfaction after refractive lens exchange and multifocal intraocular lens implantation**

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**ABSTRACT**

**Purpose:** To determine the degree of tolerance toward different magnitudes of residual refractive astigmatism and corneal astigmatism and the angles of corneal astigmatism after implantation of an asymmetric multifocal intraocular lens (IOL).

**Setting/Venue:** Cathedral Eye Clinic, Belfast, United Kingdom.

**Design:** Retrospective comparative case series.

**Methods:** The study enrolled patients having refractive lens exchange and implantation of a Lentis Mplus LS-312 MF30 IOL. Uncorrected (UDVA) and corrected distance visual acuities, uncorrected near and intermediate visual acuities, and quality-of-vision questionnaires were evaluated. Groups were categorized based on the magnitude of refractive astigmatism and corneal residual astigmatism. Refractive astigmatism of less than 0.50 diopter (D) and more than 0.50 D and corneal astigmatism of 0.50 D or less, 0.51 to 0.75 D, 0.76 to 1.00 D, and more than 1.00 D were categorized.

**Results:** The study comprised 117 patients (234 eyes). There was a significant difference in UDVA ($P = .003$), refractive sphere ($P = .001$), and defocus equivalent ($P \leq .001$) between the residual refractive astigmatism groups; however, there was no difference in quality of vision ($P = .28$). The same was found for corneal astigmatism with UDVA ($P \leq .001$) and quality of vision ($P = .16$). The angle of corneal astigmatism in relation to IOL placement did not statistically affect postoperative outcomes.

**Conclusions:** The IOL appeared to subjectively tolerate residual astigmatism well despite a statistically significant difference in UDVA with higher magnitudes of residual astigmatism. The angle of residual corneal astigmatism in relation to IOL placement did not have a significant effect on postoperative outcomes.

## INTRODUCTION

Multifocal intraocular lens (IOL) technology is often used in modern cataract extraction surgery and refractive procedures, providing excellent levels of visual performance at a range of distances (Leyland and Zinicola, 2003; Javitt and Steinert, 2000; Chiam et al., 2006; Cillino et al., 2008) as well as spectacle independence (Lubiński et al., 2014; Zhang et al., 2011). However, not all patients are content postoperatively. Reported problems include reduced contrast and the presence of glare, halos, and/or starbursts around lights (Leyland and Zinicola, 2003; Montés-Micó and Alió, 2003). Patients might also report substandard near or intermediate vision, which affects their ability to see clearly at different working distances (Hütz et al., 2008; Blaylock et al., 2006).

It is important to consider what produces these negative side effects and reduces overall patient satisfaction. One factor that appears to affect postoperative vision and quality of life is uncorrected astigmatism (Wolffsohn et al., 2011). In various multifocal IOL studies, patients reported blurred vision, which in the majority of cases was caused by ametropia and/or astigmatism, a well-recognized cause of patient dissatisfaction with symmetrical multifocal IOLs (de Vries et al., 2011; Woodward et al., 2009). The effect of astigmatism on uncorrected distance visual acuity (UDVA) has been shown to have a greater effect with symmetrical multifocal IOLs than with monofocal IOLs (Hayashi et al., 2000).

New-generation, rotationally asymmetric multifocal IOLs differ from rotationally symmetrical multifocal IOLs because they have only 2 sections-a surface embedded near section and a larger distance section-providing 2 different foci. This is in contrast to the concentric rings found in previous multifocal IOL designs. With only

2 transition zones, rotationally asymmetric multifocal IOLs provide excellent visual results, reduce dysphotopsic side effects (Alió et al., 2011), and improve contrast sensitivity (Alió et al., 2012).

To our knowledge, the effect of uncorrected residual astigmatism on this new asymmetric multifocal IOL design has not been evaluated. Therefore, this study sought to determine and quantify, where possible, the effect of residual refractive astigmatism on subjective quality of vision after asymmetric multifocal IOL implantation. The effect of postoperative corneal astigmatism and the relationship between the multifocal IOL position and the angle of the steepest corneal meridian on subjective quality of vision was also measured. The aim of this study was to determine the degree of tolerance patients have to different levels of residual astigmatism and to the angle of this astigmatism in relation to the position of the asymmetric multifocal IOL before there is a significant deleterious effect on quality of vision.

**Patients and methods**

This study enrolled patients having refractive lens exchange (RLE) with bilateral implantation of Lentis Mplus LS-312 MF30 multifocal IOLs (Oculentis GmbH). Informed consent was obtained from all patients for their anonymised data to be submitted for audit and publication. The patients were advised of the possible risks associated with the operation and the possible need for further corneal laser refractive surgery.

The patients were first divided into 2 groups depending on the magnitude of residual refractive astigmatism ($\leq$ 0.50 diopter [D] or > 0.50 D) found after subjective refraction. Patients were then categorized into 4 groups based on the magnitude of postoperative corneal astigmatism (≤ 0.50 D, 0.51 to 0.75 D, 0.76 to 1.00 D, or >1.00 D). The postoperative corneal astigmatism was measured using the OPD-Scan II ARK-10000 aberrometer (Nidek Co., Ltd.). The magnitude of corneal astigmatism was defined as the difference between the steep and flat corneal meridians. Patients with corneal astigmatism greater than 0.50 D were then categorized by the angle of the steepest corneal meridian in relation to the position of the multifocal IOL (Figure 1).

Preoperatively at the slitlamp, the horizontal and vertical axes were marked at the limbus. The multifocal IOL was implanted with the near segment positioned inferiorly and nasally deviated halfway between the vertical and horizontal limbal marks. Therefore, the long axis of the multifocal IOL was positioned at approximately 135 degrees in the right eye and at approximately 45 degrees in the left eye. Patients with the steepest meridian from 0 to 22.5 degrees, 158.0 to 180.0 degrees, and 68.0 to 112.5 degrees in the right eye or the left eye were considered to obliquely cross the vertical axis. Patients with the steepest meridian at an angle of 23.0 to 67.5 degrees in the right eye and an axis of 113.0 to 157.5 degrees in the left eye were categorized together because they both crossed perpendicularly to the vertical axis. Patients with an axis of 113.0 to 157.5 degrees in the right eye and 23.0 to 67.5 degrees in the left eye were grouped together because the steepest meridian ran parallel to the vertical axis in the respective eyes.

**Patient Assessment**

A full ophthalmologic assessment was performed preoperatively and postoperatively. The examination included a medical history, autorefraction using the aberrometer, subjective refraction (RT-5100 Auto Phoropter Head, Nidek Co., Ltd.), UDVA, corrected distance visual acuity, defocus equivalent based on subjective refraction, and uncorrected near (UNVA) and uncorrected intermediate (UIVA) visual acuities. These results were evaluated with logMAR charts (6 m) and with Radner reading charts in M notation (40 cm and 70 cm). Biometry was performed preoperatively with the IOLMaster device (Carl Zeiss Meditec AG). Pupil size, corneal topography, angle k, and wavefront examinations were performed with the aberrometer. The software of the aberrometer was used to report higher-order aberrations (HOAs) across a 6.0 mm pupil up to the 6th radial order (Thibos et al., 2002). Aberrations above the 6th order have an extremely small impact on the overall aberration (McAlinden et al., 2011). Slitlamp microscopy, tonometry, dilated fundoscopy, and optical coherence tomography of the retina were completed. Each patient was assessed within 6 weeks postoperatively and then at 6 months. The position of the vertical axis of the multifocal IOL was assessed postoperatively to confirm an axis of 135 degrees in the right eye and 45 degrees in the left eye.

A quality-of-vision (QoV) questionnaire was completed preoperatively and at the second postoperative assessment. This evaluated the extent to which the patients were bothered by the listed symptoms. The patients were asked to respond with not at all (0), a little (1), quite (2), or very (3). The patients also rated their vision from 0 to 10, with 0 representing the worst and 10 representing the best.

**Intraocular Lens**

The Lentis Mplus is a rotationally asymmetric multifocal IOL consisting of an aspheric distance-vision zone and a separate sector-shaped near-vision zone. It has a refractive design with a seamless transition between the 2 sections of the multifocal IOL. This multifocal IOL is available with a +1.50 D, +2.00 D, or +3.00 D near-segment addition (add). In this study, each patient had bilateral implantation of the Lentis Mplus LS-312 MF30 IOL (+3.00 D add).

**Surgical Technique**

The same experienced surgeon (J.E.M.) performed all operations with standard on-axis clear corneal phacoemulsification. An incision of 2.75 mm was used to reduce postoperative corneal astigmatism, and the incision was made on the steepest meridian to evade the introduction of oblique astigmatism. A 5.00 mm capsulorhexis was created, and implantation of the multifocal IOL in the capsular bag was performed. The vertical axis (near segment) was positioned inferiorly with a slight nasal deviation in each eye. The refractive aim was emmetropia.

**Statistical Analysis**

Descriptive and statistical analysis was performed using SPSS forWindows software (version 22, SPSS, Inc.) and Excel software (Microsoft Corp.). The Kolmogorov-Smirnov test was used to assess normality. Independent t tests and 1-way analysis of variance were used for parametric data with a post hoc Tukey test to compare the results between groups. The Kruskal-Wallis test was used to compare nonparametric data and the Wilcoxon signed-rank test was used to compare nonparametric data between groups. A paired-sample t test was also used to test the significance between preoperative HOAs and postoperative HOAs. For all statistical analyses, the level of significance was a P value less than 0.05.

**Results**

This study included 117 patients (234 eyes). Table 1 shows the patients' demographics.

<u>Magnitude of Residual Refractive Astigmatism</u>

Figure 2 (top) displays the linear regression analysis between the residual refractive astigmatism and the UDVA, where a weak correlation was found ($R^2$ = 0.12). Figure 2 (bottom) shows a slightly stronger association between UDVA and the defocus equivalent

($R^2$ = 0.23). The patients were then divided into 2 groups based on postoperative refractive cylinder as follows: 0.50 D or less (216 eyes) and greater than 0.50 D (18 eyes). Table 2 shows the objective results in the 2 groups. The group with residual refractive astigmatism of 0.50 D or less achieved better UDVA than those with more than 0.50 D (P = .003, independent *t* test). There was also a greater magnitude of defocus equivalent in the group with more than 0.50 D ($P \leq .001$, independent *t* test). Figure 3 shows the individual symptom responses between the 2 groups, and Figure 4 shows the QoV scores. There was no significant difference in individual responses or QoV scores (P = .28, independent *t* test).

Magnitude of Residual Corneal Astigmatism

The 0.50 D or less corneal astigmatism group comprised 99 eyes; the 0.51 to 0.75 D group, 53 eyes; the 0.76 to 1.00 D group, 41 eyes; and the more than 1.00 D group, 41 eyes. The mean corneal astigmatism postoperatively was 0.63 D ± 0.36 (SD). Patients with corneal astigmatism of 0.50 D or less achieved significantly better UDVA than those with 0.76 to 1.00 D and those with more than 1.00 D (Table 3). There was no significant difference in individual symptoms or overall QoV scores between the groups.

Residual Corneal Astigmatism Axis in Relation to the Multifocal Intraocular Lens

There were 135 eyes with corneal astigmatism greater than 0.50 D, 99 in the oblique group, 22 in the perpendicular group, and 14 in the parallel group. There was no significant difference in objective outcomes between eyes with varying angles of corneal astigmatism (Table 4). In 60 patients, the steepest corneal meridian crossed the vertical axis of the multifocal IOL in each eye. In 13 patients, the steepest corneal meridian crossed perpendicular to the vertical axis in each eye. In 6 patients, there was a parallel relationship to the multifocal IOL in each eye. There was no significant difference in individual listed symptoms and overall QoV scores between the groups (Figure 5).

**Discussion**

It is common to have varying levels of residual astigmatism after RLE, and its magnitude can be difficult to predict because of multiple dependent factors (Norrby, 2008). Residual refractive astigmatism affects visual acuity (Hayashi et al., 2000; Hayashi et al., 2010) and is a main cause of blurred vision (de Vries et al., 2011; Woodward et al., 2009) after implantation of monofocal IOLs and of multifocal IOLs. However, it is not known how residual astigmatism affects eyes with asymmetric multifocal IOLs. Therefore, this study sought to determine what effect residual refractive astigmatism and corneal astigmatism have on the quality of vision after implantation of the Lentis Mplus LS-312 MF30 asymmetric multifocal IOL.

The current study found a significant difference in UDVA between patients who had 0.50 D or less of residual refractive astigmatism than patients who had more than 0.50 D. Also, the defocus equivalent was greater in eyes with more than 0.50 D of residual refractive astigmatism, confirming that the defocus equivalent was not a significant cofounding factor on the effect of increasing cylinder on UDVA. There was no significant difference in UNVA or UIVA between the 2 residual refractive astigmatism groups.

With traditional symmetrical multifocal IOLs, distance visual acuity is significantly affected by uncorrected astigmatism. Hayashi et al., (2010) found that with 0.50 D, 1.00 D, 1.50 D, and 2.00D of simulated astigmatism, distance visual acuity was significantly reduced at each magnitude of astigmatism with both a +3.00 D add and a +4.00 D add symmetrical multifocal IOL (Acrysof Restor, Alcon Laboratories, Inc.). The same was found for monofocal IOLs; however, the reduction in distance visual acuity was worse with the multifocal IOLs. There was no significant difference in distance visual acuity up to 1.00 D between the multifocal IOLs and monofocal IOLs, and with astigmatism of 1.50 D and greater, the distance and intermediate vision was better with monofocal IOLs. The near visual acuity was significantly better in the multifocal IOL group with up to 1.00 D of astigmatism. This study suggests that the multifocal IOLs are useful for up to 1.00 D of astigmatism. In a study by Hayashi et al., (2000) of symmetrical multifocal IOLs (Array, Abbott Medical Optics, Inc.), the fraction of eyes that achieved 0.16 logMAR acuity decreased for every 0.50 D of astigmatism. Of the 30 eyes in their study, 24 achieved 20/29 (0.16 logMAR) acuity at distance and 20/50 (0.40 logMAR) at near with no astigmatism; 21 eyes with 0.50 D, 13 eyes with 1.00 D, 8 eyes with 1.50 D, and no eye with 2.00 D or 2.50 D of astigmatism achieved this level of acuity. This study also compared these results with a monofocal IOL and found that the multifocal IOL group achieved a significantly worse distance visual acuity with 0.50 D, 1.00 D, and 1.50 D of astigmatism; however, the near visual acuity was better in the multifocal IOL group. With higher levels of astigmatism (2.00 D and 2.50 D), the multifocal IOL group had significantly worse distance and intermediate visual acuity than the monofocal group. The authors concluded that residual astigmatism affects multifocal IOLs more than monofocal IOLs. These studies found that residual astigmatism has an effect on visual acuity at all distances; however, it appears the multifocality of multifocal IOLs is not affected until the astigmatism is greater than 1.00 D. It appears that monofocal IOLs are better for distance and intermediate vision when the astigmatism is greater than 1.00 D.

In our study, only 18 eyes had astigmatism of 0.75 D or more because our refractive aim was emmetropia. This is a shortcoming of our study because it allowed us to evaluate only 2 groups with differing magnitudes of residual refractive astigmatism.

It would be beneficial to have more groups to allow a more detailed analysis between different magnitudes of astigmatism to determine the exact level at which visual performance begins to be affected. However, in our study, there was a statistically significant difference in UDVA between the groups. Therefore, it would appear that in our study, the objective UDVA was affected by increasing levels of astigmatism in a fashion similar to that for symmetrical multifocal IOLs (Hayashi et al., 2000); however, eyes with more than 0.50 D of residual refractive astigmatism still had an excellent level of unaided visual acuity. As discussed in the study by Hayashi et al., (2000) 21 (70%) out of 30 eyes achieved distance visual acuity of 0.16 logMAR and 0.40 logMAR for near visual acuity with 1.00 D and 1.50 D of astigmatism. In our study, 14 (77%) of 18 patients with astigmatism of 0.75 D and above achieved distance and near visual acuity of this level. However, unlike previous studies of symmetrical multifocal IOLs, the residual refractive astigmatism did not negatively affect UNVA or UIVA (Hayashi et al., 2010). A further analysis of objective findings with asymmetric multifocal IOLs is required, and a direct comparison with traditional symmetrical multifocal IOLs and monofocal IOLs would be beneficial.

Objective outcomes give an indication of visual performance only; therefore, we sought to determine how residual refractive astigmatism affects subjective outcomes through the use of a QoV questionnaire. There was no significant difference between the 2 groups for each of the symptoms on the questionnaire.

In a study by de Vries et al., (2011) of 76 eyes with a diffractive multifocal IOL, 64.5% of patients reported blurred vision related to ametropia or astigmatism. The overall mean refractive cylinder was 0.95 D. In another study of 43 eyes with diffractive multifocal IOLs Woodward et al., 2009), 25% had residual astigmatism of 0.75 D or more and patients who reported blurred vision had a mean astigmatism of 1.55 D compared with the other patients, who had a mean astigmatism of 0.53 D. A previous study (Dick et al., 1999) found that patients with multifocal IOLs and astigmatism of more than 1.00 D reported significantly bigger halos than patients who had astigmatism of less than 1.00 D. This contrasts with the findings in our study in which there was no significant difference in subjective visual symptoms, such as glare and dysphotopsias, between the groups. However, our results with this asymmetric multifocal IOL were in broad agreement with those in a study by Dick et al., (1999) of patients with monofocal IOLs, which found no significant difference in the frequency of reported halos and glare symptoms between patients with less than 1.00 D of astigmatism and those with more than 1.00 D of astigmatism.

An important aspect of the QoV questionnaire used in our study is that the patient was asked to report his or her overall quality of vision on a scale of 0 to 10. This provides an overall indication of how satisfied an individual is with his or her quality of vision. In the current study, all groups had excellent QoV scores with no significant difference between the groups. Although there is a significant difference in UDVA with higher residual refractive astigmatism, similar to that with symmetrical multifocal IOLs, this is not reflected in individual symptom responses or in the overall QoV scores. Because there was only 1 case with higher levels of residual defocus equivalent greater than 1.50 D, it is difficult to determine absolute patient tolerances; however, no one in this cohort required further laser refractive surgery despite its free availability. It would appear that asymmetric multifocal IOLs are subjectively more tolerant to higher degrees of astigmatism.

There was some disparity between the refractive astigmatism and the corneal astigmatism postoperatively. This might be related in part to measurement error or to the multifocal IOL internally affecting the total refractive astigmatism. However, accurate measurement of this can be somewhat difficult with the OPD-Scan II ARK-10000 aberrometer because of the inability of Zernike polynomials to adequately decompose wavefront aberrations from the distance and juxtaposed near add. Characteristically, this can be interpreted in the aberrometer as coma rather than simply as an increase in spherical power in the near add (de Wit et al., 2015). The current study found a significant increase only in trefoil aberrations from preoperatively to postoperatively, which again might be inaccurate because of the aforementioned problems. Therefore, we assessed the isolated effect of corneal astigmatism on objective outcomes and on patient satisfaction. The mean corneal astigmatism in our study was $0.63 \pm 0.36$ D and is comparable to that in a study by Elkady et al., (2008) which found a mean astigmatism of $0.63 \pm 0.62$ D after microincision cataract surgery. In our study, the level of UDVA was significantly worse than the UDVA in the 0.50 D or less group when astigmatism was 0.76 to 1.00 D ($P \leq .001$) and more than 1.00 D ($P \leq .001$); however, again the UDVA remained at an excellent clinical level. Similar to the previously assessed refractive astigmatism, this difference in UDVA did not appear to affect patient satisfaction because no significant difference was found between the postoperative corneal groups. Similarly, with residual refractive astigmatism, there was no significant difference in reports of blurred vision and halos, as has been found with increasing levels of induced astigmatism (de Vries et al., 2011; Woodward et al., 2009; Dick et al., 1999).

We also sought to determine the effect of the corneal astigmatism axis in relation to the vertical axis of the asymmetric multifocal IOL on postoperative objective and subjective outcomes. To our knowledge, this is the first study to determine the effect of uncorrected astigmatism on asymmetric multifocal IOLs and, therefore, is the first study to determine the effect of the axis on postoperative outcomes. In this study, we found that the relationship between the vertical axis of the multifocal IOL and the corneal astigmatism did not have a significant effect on objective or subjective outcomes.

In summary, in this study, the UDVA with the asymmetric multifocal IOL was significantly affected by residual astigmatism; however, UNVA and UIVA appeared to be unaffected. In addition, an increasing magnitude of residual astigmatism did not significantly affect the subjective outcomes. Also, when implanting an asymmetric multifocal IOL inferiorly with nasal displacement, the angle of the steepest corneal meridian in relation to this placement did not affect the objective outcomes or the overall subjective quality of vision. This gives the clinician a better understanding of the effects on patient satisfaction of residual astigmatism after RLE, and it will help the surgeon determine the clinical management of residual astigmatism.

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**FIGURES & TABLES**

**Figure 1 -** Relationship between the position of the multifocal IOL and the various categorized angles of residual astigmatism. The vertical axis of the multifocal IOL (reading segment inferiorly and nasally displaced) is represented by the line at 135 degrees in the right eye and 45 degrees in the left eye. *Top row:* Angles from 0 to 22.5 degrees and 68.0 to 112.5 degrees in the right eye and left eye cross the vertical axis of the multifocal IOL obliquely and are categorized together in the oblique group. *Middle row:* Angles from 23.0 to 67.5 degrees in the right eye and 113.0 to 157.5 degrees in the left eye cross the multifocal IOL perpendicularly and are categorized together in the perpendicular group. *Bottom row:* Angles from 113.0 to 157.5 degrees in the right eye and 23.0 to 67.5 degrees in the left eye cross the multifocal IOL perpendicularly and are categorized together in the parallel group.

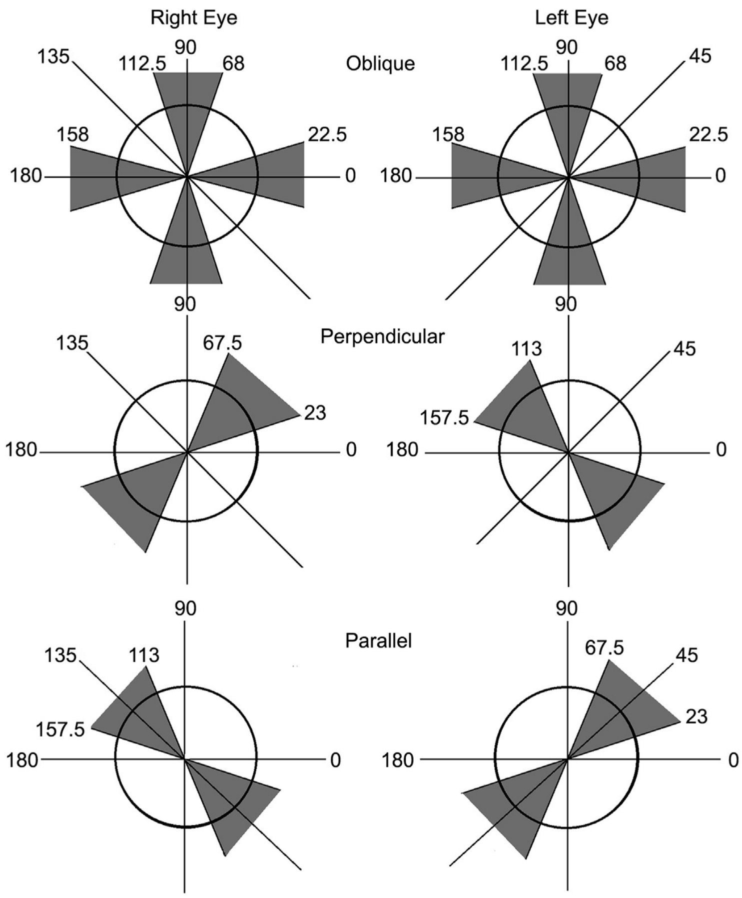
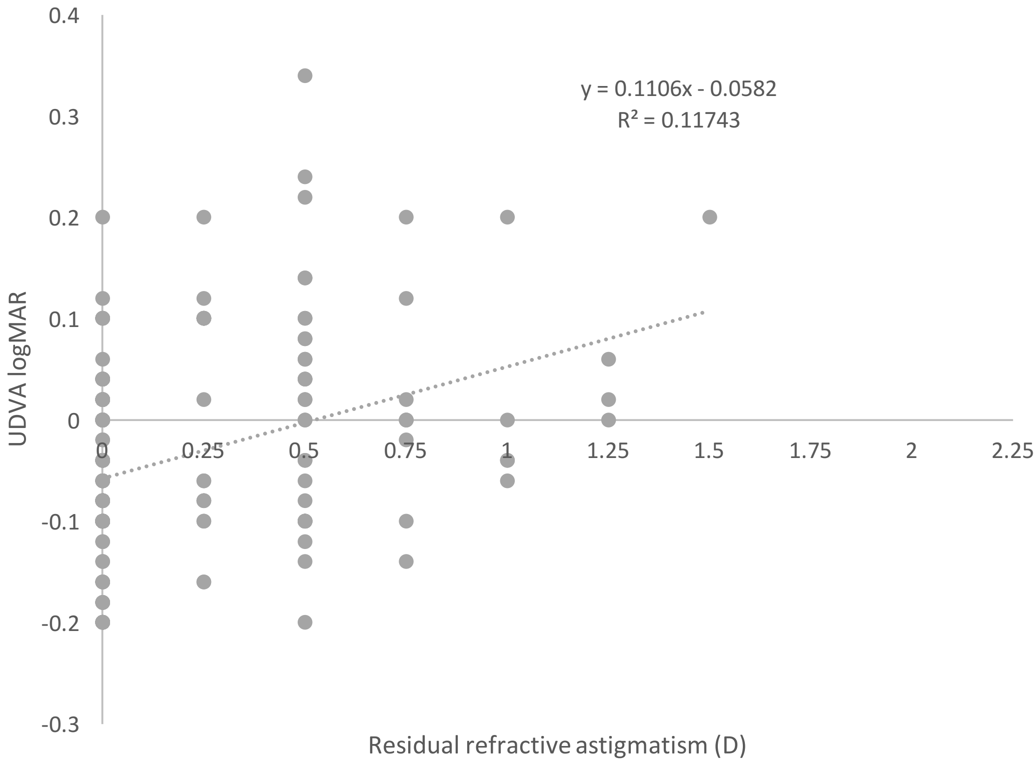
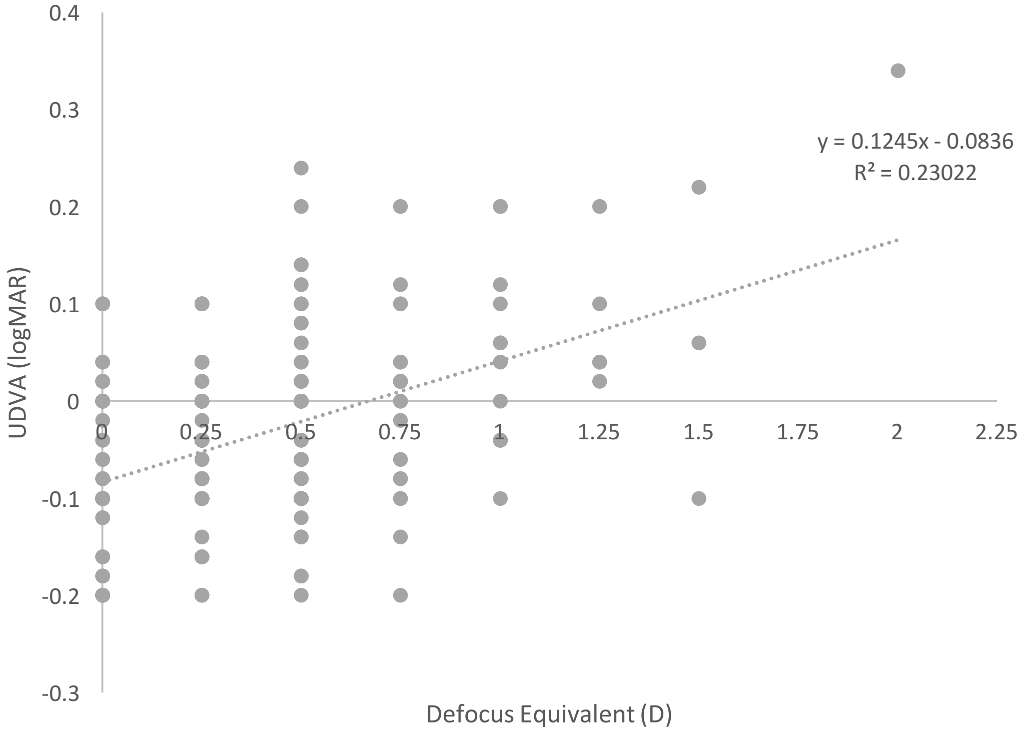


**Figure 2 -** *Top:* Assessment of the relationship between the residual refractive astigmatism and UDVA 6 months postoperatively (234 eyes). *Bottom:* Linear regression analysis of the weak relationship between the defocus equivalent and UDVA 6 months postoperatively (234 eyes) (UDVA = uncorrected distance visual acuity).





0.4
0.3
0.2
0.1
0
-0.1
-0.2
-0.3
UDVA (logMAR)
0
0.25
0.5
0.75
1
1.25
1.5
1.75
2
2.25
y = 0.1245x - 0.0836
R² = 0.23022
Defocus Equivalent (D)

**Figure 3 -** The mean overall individual symptom scores for different magnitudes of residual refractive astigmatism 6 months postoperatively (234 eyes). The x-axis shows the symptom responses (0 = not at all, 1 = a little, 2 = quite, 3 = very) and the y-axis, the QoV score. A higher mean score indicates the patient was more affected by the symptom (Cyl = cylinder).

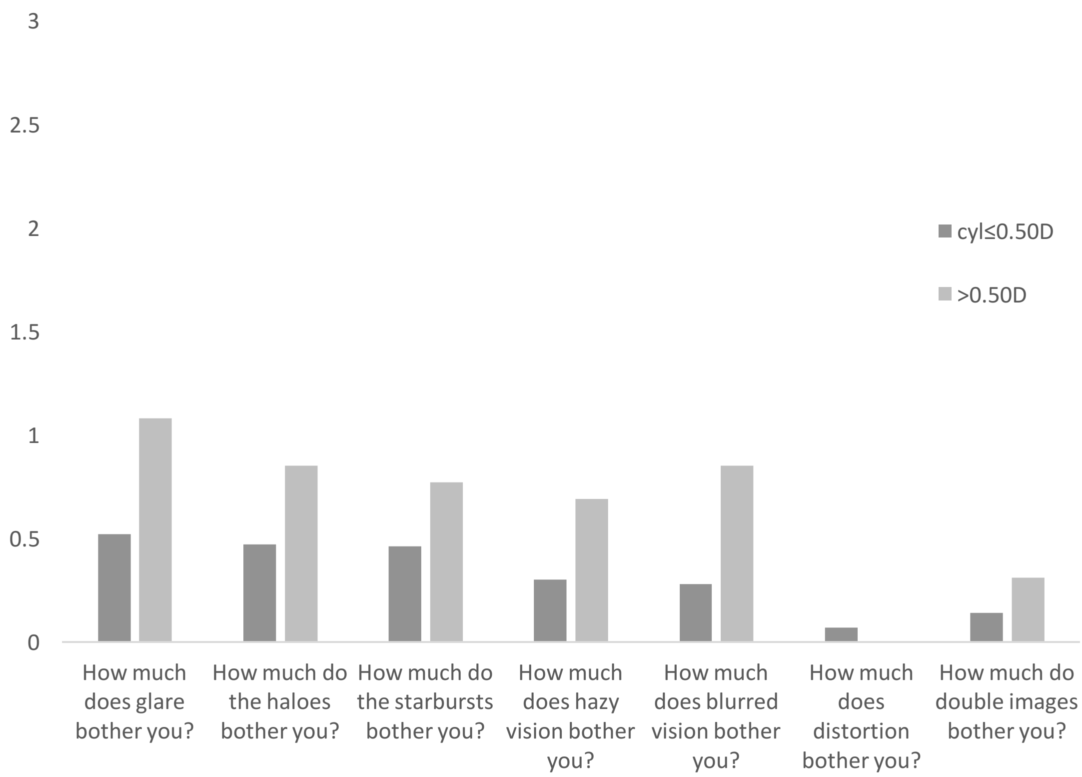
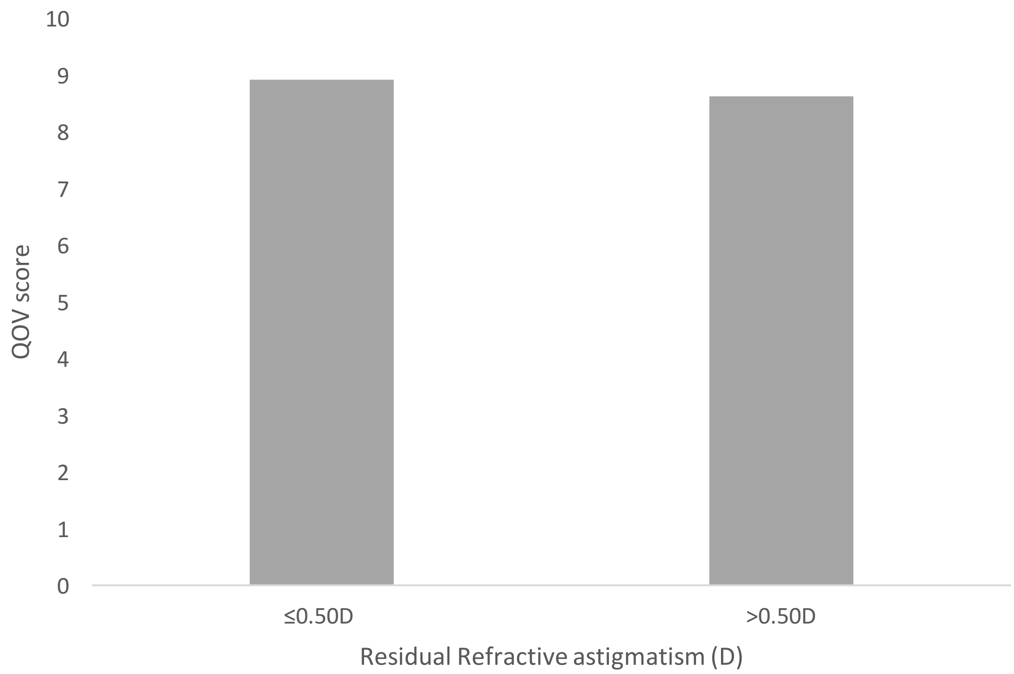


**Figure 4 –** *Top:* The mean overall QoV scores for different magnitudes of residual refractive astigmatism 6 months postoperatively (234 eyes). *Bottom:* Box plot of the QoV scores for the different magnitudes of residual refractive astigmatism 6 months postoperatively (234 eyes). (0 = the worst; 10 = the best) (QoV = quality-of-vision questionnaire).



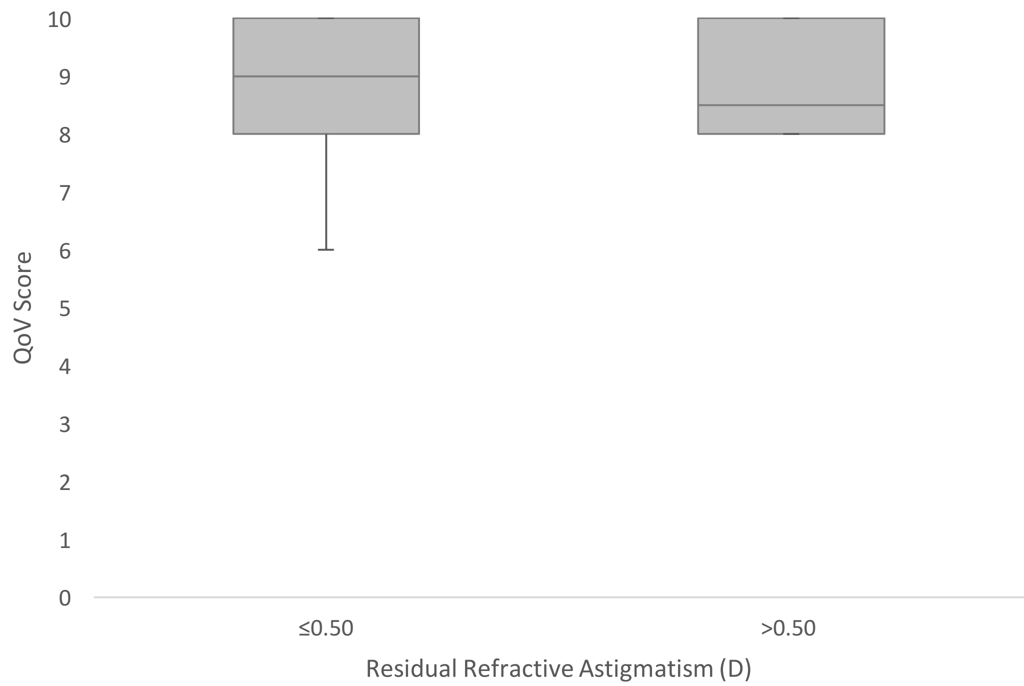
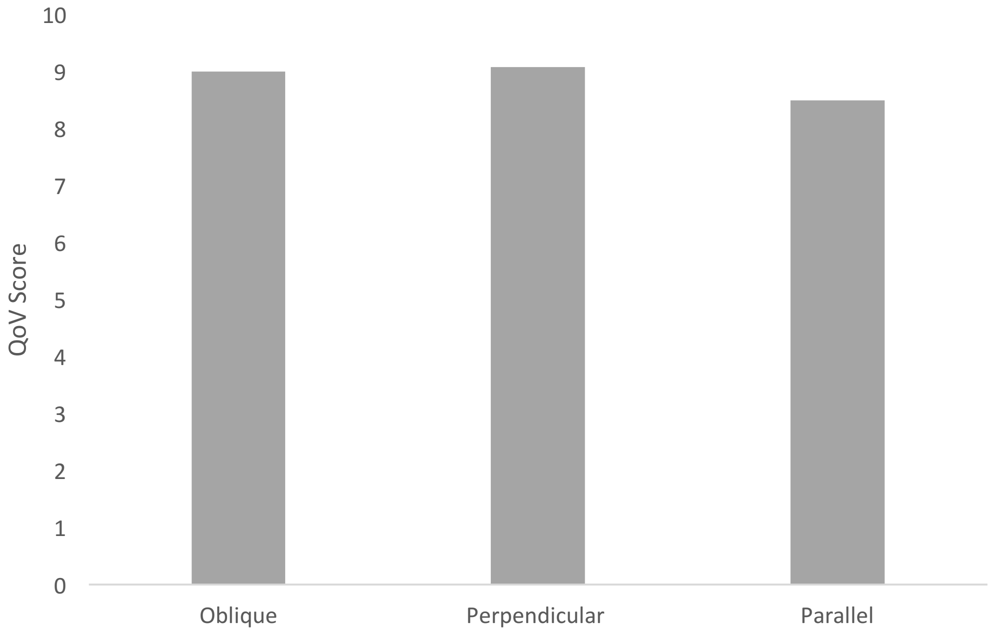



**Figure 5 –** *Top:* The overall QoV scores for different angles of residual corneal astigmatism in relation to the position of the multifocal IOL. *Bottom:* Box plot of the overall QoV scores for different angles of residual corneal astigmatism in relation to the position of the multifocal IOL. (QoV = quality-of-vision questionnaire).



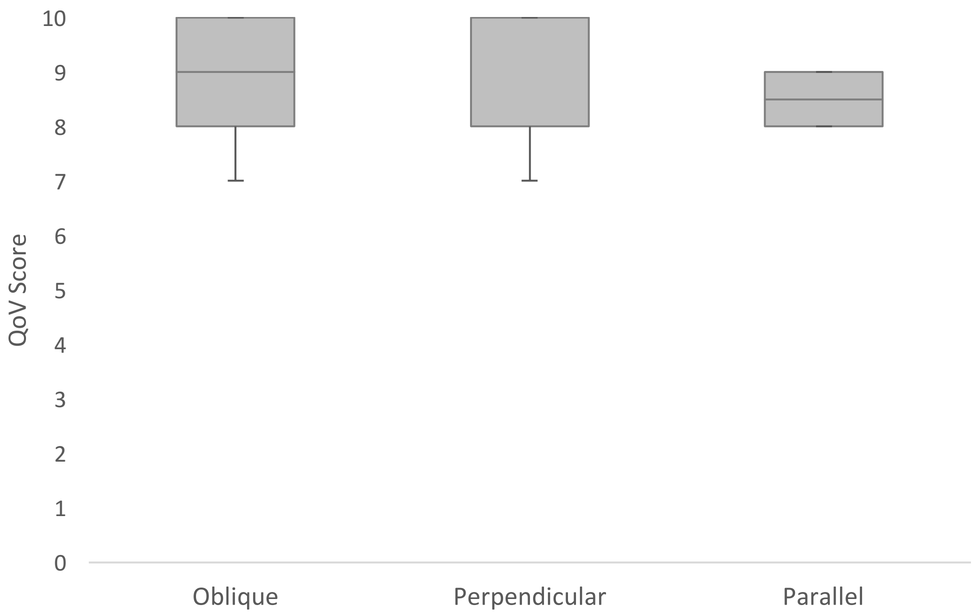



**Table 1 –** Patient Demographics

| Parameter | Number |
|---|---|
| **Patients (n)** | 117 |
| **Male, n (%)** | 48 (41) |
| **Female, n (%)** | 69 (59) |
| **Age (y)** | |
| Mean ± SD | 64 ± 8.31 |
| Median | 64 |
| Range | 44, 87 |
| **Sphere (D)** | |
| Mean ± SD | 0.41 ± 3.83 |
| Median | 1.50 |
| Range | -16.50, 5.75 |
| **Cylinder (D)** | |
| Mean ± SD | -0.56 ± 0.56 |
| Median | -0.50 |
| Range | -2.25, 0 |
| **LogMAR CDVA** | |
| Mean ± SD | 0.01 ± 0.12 |
| Median | 0 |
| Range | -0.20, 0.60 |
| *CDVA= corrected distance visual acuity* | |

**Table 2 -** Objective outcome comparisons between groups with different magnitudes of residual refractive astigmatism at the second postoperative assessment (6 months).

| | **≤0.50 D (n=216)** | **>0.50D (n=18)** | **P Value** |
|---|---|---|---|
| **LogMAR UDVA** | | | |
| Mean ± SD | -0.05 ± 0.09 | 0.02 ± 0.10 | 0.003 |
| Range | -0.20, 0.34 | -0.14, 0.20 | |
| **Sphere (D)** | | | |
| Mean ± SD | 0.08 ± 0.38 | 0.51 ± 0.47 | 0.001 |
| Range | -1.50, 1.50 | -0.25, 0.75 | |
| **Defocus equivalent (D)** | | | |
| Mean ± SD | 0.31 ± 0.34 | 0.83 ± 0.24 | <0.001 |
| Range | 0, 2.00 | 0.50, 1.25 | |
| **UNVA (M notation)** | | | |
| Mean ± SD | 0.60 ± 0.17 | 0.64 ± 0.23 | 0.35 |
| Range | 0.32, 1.60 | 0.40, 1.25 | |
| **UIVA (M notation)** | | | |
| Mean ± SD | 0.96 ± 0.24 | 1.10 ± 0.38 | 0.15 |
| Range | 0.50, 2.00 | 0.80, 2.00 | |

*UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity ; UIVA = uncorrected intermediate visual acuity*

**Table 3 -** Objective outcome comparisons between groups with different magnitudes of corneal astigmatism at the second postoperative assessment (6 months).

| | **≤0.50 D (n=99)** | **0.51D to 0.75D (n=53)** | **0.76D to 1.00D (n=41)** | **>1.00D (n=41)** | **P Value** |
|---|---|---|---|---|---|
| **LogMAR UDVA** | | | | | |
| Mean ± SD | -0.07 ± 0.08 | -0.05 ± 0.09 | 0 ± 0.08 | 0 ± 0.11 | <0.001 |
| Range | -0.20, 0.20 | -0.20, 0.24 | -0.16, 0.20 | -0.20, 0.34 | |
| **Sphere (D)** | | | | | |
| Mean ± SD | 0.10 ± 0.34 | 0.13 ± 0.46 | 0.16 ± 0.42 | 0.06 ± 0.45 | 0.72 |
| Range | -0.50, 1.25 | -1.00, 1.50 | -0.50, 1.25 | -1.50, 1.00 | |
| **Defocus equivalent (D)** | | | | | |
| Mean ± SD | 0.28 ± 0.30 | 0.37 ± 0.43 | 0.39 ± 0.33 | 0.43 ± 0.43 | 0.11 |
| Range | 0, 1.25 | 0, 1.50 | 0, 1.25 | 0, 2.00 | |
| **UNVA (M notation)** | | | | | |
| Mean ± SD | 0.58 ± 0.16 | 0.62 ± 0.20 | 0.65 ± 0.24 | 0.58 ± 1.26 | 0.14 |
| Range | 0.40, 1.25 | 0.32, 1.25 | 0.40, 1.60 | 0.40, 0.80 | |
| **UIVA (M notation)** | | | | | |
| Mean ± SD | 0.95 ± 0.20 | 0.97 ± 0.28 | 0.99 ± 0.20 | 1.04 ± 0.38 | 0.45 |
| Range | 0.80, 1.60 | 0.63, 1.60 | 0.80, 1.25 | 0.50, 2.00 | |

*UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuit ; UIVA = uncorrected intermediate visual acuity*

**Table 4 -** Objective outcome comparisons between groups with different angles of corneal astigmatism greater than 0.50 D at the second postoperative assessment (6 months or more).

| | **Oblique axis groups (n=99)** | **Perpendicular (n=22)** | **Parallel (n=14)** | **P Value** |
|---|---|---|---|---|
| **UDVA (LogMAR)** | | | | |
| Mean ± SD† | -0.03 ± 0.10 | 0.01 ± 0.10 | 0 ± 0.08 | 0.23 |
| Range | -0.20, 0.34 | -0.10, 0.22 | -0.10, 0.20 | |
| **Sphere (D)** | | | | |
| Mean ± SD | 0.12 ± 0.42 | 0.08 ± 0.61 | 0.16 ± 0.33 | 0.87 |
| Range | -1.50, 1.25 | -1.00, 1.50 | 0, 1.25 | |
| **Cylinder (D)** | | | | |
| Mean ± SD | -0.22 ± 0.35 | -0.18 ± 0.22 | -0.18 ± 0.42 | 0.80 |
| Range | -1.25, 0 | -0.50, 0 | -1.50, 0 | |
| **UNVA (M notation)** | | | | |
| Mean ± SD | 0.62 ± 0.21 | 0.62 ± 0.15 | 0.57 ± 0.10 | 0.65 |
| Range | 0.40, 1.60 | 0.32, 1.00 | 0.40, 0.80 | |
| **UIVA (M notation)** | | | | |
| Mean ± SD | 1.02 ± 0.32 | 0.96 ± 0.22 | 0.94 ± 0.21 | 0.60 |
| Range | 0.50, 2.00 | 0.63, 1.25 | 0.80, 1.25 | |

*UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity; UIVA = uncorrected intermediate visual acuity*

## 7. PAPER-VI

**Comparison of the visual performance and quality of vision with combined symmetrical inferonasal near addition versus inferonasal and superotemporal placement of rotationally asymmetric refractive multifocal intraocular lenses**

Richard N. McNeely, Eric Pazo, Andrew Spence, Olivier Richoz, M. Andrew Nesbit, Tara C.B. Moore, Jonathan E. Moore.

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**Contributions**

Richard N. McNeely – *concept and design, data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Eric Pazo – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Andrew Spence – *data acquisition, data analysis/interpretation, drafting manuscript, statistical analysis*

Olivier Richoz – *data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis*

M. Andrew Nesbit – *critical revision of manuscript, supervision*

Tara C.B. Moore – *critical revision of manuscript, supervision*

Jonathan E. Moore – *concept and design, data acquisition, data analysis/interpretation, critical revision of manuscript, statistical analysis, supervision*

**Comparison of the visual performance and quality of vision with combined symmetrical inferonasal near addition versus inferonasal and superotemporal placement of rotationally asymmetric refractive multifocal intraocular lenses**

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**ABSTRACT**

**Purpose:** To compare the postoperative quality of vision between different bilateral placements of near segments of rotationally asymmetric refractive multifocal intraocular lenses (IOLs) and to determine how this affects visual performance.

**Setting/Venue:** Cathedral Eye Clinic, Belfast, Northern Ireland, United Kingdom.

**Design:** Retrospective comparative case series.

**Methods:** The study enrolled consecutive patients having refractive lens exchange and implantation of rotationally asymmetric multifocal IOLs. Group 1 received bilateral SBL-3 IOLs and Group 2 received bilateral Lentis Mplus LS-312 MF30 IOLs, with the near segments placed inferonasally in each group. Group 3 received a Lentis Mplus LS-312 MF20 IOL in the dominant eye with the near segment positioned superotemporal and a Lenstec SBL-3 IOL positioned inferonasally in the fellow eye. Binocular uncorrected (UDVA) and corrected distance visual acuities, binocular uncorrected near (UNVA) and intermediate (UIVA) visual acuities, binocular distance-corrected near and intermediate visual acuities, and quality of vision were evaluated over 3 months postoperatively.

**Results:** The study enrolled 180 patients (360 eyes). There was no significant difference between the groups in binocular UDVA, UIVA, and UNVA; however, there was a significant difference between the groups in quality of vision ($P \leq .001$). Group 3 had significantly better overall quality of vision.

**Conclusion:** When implanting rotationally asymmetric multifocal IOLs, a combination of superotemporal placement of the near segment (+2.00 diopter [D] addition [add]) in the dominant eye with inferonasal placement of the near segment (+3.00 D add) in the fellow eye yielded consistent, high overall quality of vision and uncorrected visual acuity.

**INTRODUCTION**

Rotationally asymmetric refractive multifocal intraocular lenses (IOLs) have been used in modern lens based surgery for the past 7 years. The Lentis Mplus (Oculentis GmbH) was the first commercially available asymmetric multifocal IOL, and many studies (Alió et al., 2012a; Alió et al., 2012b; Rosa et al., 2013; Ramón et al., 2012; Alió et al., 2011a) have outlined its performance, advantages, and shortcomings. A second asymmetric multifocal IOL, the SBL-3 (Lenstec, Inc.), has since been introduced and an initial study by Venter et al., (2014) found that this multifocal IOL also provides a good range of near, intermediate, and distance vision.

Asymmetric multifocal IOLs provide their multifocality through a refractive design by incorporating a near vision section in the IOL. Therefore, the IOL has 2 sections-a larger distance section and a smaller reading segment-creating only 1 transition zone. Because of the design of rotationally asymmetric multifocal IOLs, the position of the near segment must be considered. An asymmetric multifocal IOL can be placed in numerous rotational positions. This differs from previous multifocal IOL designs in which the IOL consisted of concentric rings, making the multifocal IOL rotationally symmetric; therefore, the rotational position of the IOL had no effect on IOL performance. The recommended placement of the reading segment when implanting either asymmetric multifocal IOL is inferiorly with slight nasal deviation; however, the near segment can be placed in various positions without significantly affecting the visual performance of the multifocal IOL. This was confirmed in a study by de Wit et al., (2015) which found that superotemporal placement was well tolerated, and anecdotal findings suggest superotemporal placement reduces dysphotopsias.

In addition to multifocal IOL placement, the appropriate selection of a reading addition (add) must also be considered because the Lentis Mplus IOL is now available in a range of near adds (+ 1.50 diopter [D], + 2.00 D, and + 3.00 D). Lower powered near-add multifocal IOLs have been found to provide good distance and intermediate vision, albeit with reduced near vision (Alió et al., 2011b). Another study found a combination of a lower add in the dominant eye combined with a high-powered add provided good visual acuity and quality of life (McAlinden and Moore, 2011). These studies show that variation from the normal placement and that a combination of high-powered and low-powered adds provide good postoperative outcomes; however, this has not been fully evaluated.

Therefore, this study compared the visual function and overall postoperative quality of vision achieved between asymmetric multifocal IOLs with variations in near segment placements and adds. We compared lower powered add asymmetric multifocal IOLs with superotemporal placement in the dominant eye combined with inferonasal placement in the nondominant eye with asymmetric multifocal IOLs with near segments placed inferonasally in each eye. This will provide surgeons with information to provide optimum postoperative satisfaction after rotationally asymmetric multifocal IOL implantation.

**Patients and methods**

This retrospective nonrandomized study recruited consecutive patients having refractive lens exchange followed by implantation of a rotationally asymmetric multifocal IOL. All patients provided informed consent for their anonymised data to be submitted for audit and publication. The patients were advised of the possible risks associated with the operation and the possible necessity for further corneal laser refractive surgery.

Patients were divided into 3 groups based on the position of the near segment. Group 1 received bilateral SBL-3 IOLs with inferonasal placement of the near segment in each eye. Group 2 received a Lentis Mplus LS-312 MF30 IOL with the near segment positioned inferonasally in both eyes. Group 3 received a Lentis Mplus LS-312 MF20 IOL with superotemporal near segment placement in the dominant eye and a SBL-3 IOL in the fellow eye with inferonasal placement. Figure 1 shows clinical retroillumination images of the multifocal IOL near segment positions.

Exclusion criteria were a history of glaucoma or retinal detachment, ocular inflammation, corneal surgery or disease, neuro-ophthalmic disease, and macular disease.

**Patient Assessment**

A full ophthalmologic assessment was performed on all patients preoperatively. The examination included a medical history, keratometry, topography, and autorefraction (OPD-Scan II ARK-10000, Nidek Co., Ltd), subjective refraction (RT-5100 Auto Phoropter Head, Nidek Co., Ltd), uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected near (UNVA) and intermediate (UIVA) visual acuities, distance-corrected near and distance-corrected intermediate visual acuities, slitlamp examination, Goldmann tonometry, dilated fundoscopy, and retinal optical coherence tomography (Cirrus 4000; Carl Zeiss Meditec AG). Biometry was performed using partial coherence interferometry

(PCI) (IOLMaster, Carl Zeiss Meditec AG). The PCI device measured corneal curvature, anterior chamber depth, and axial length (AL) for subsequent IOL calculation using the Hoffer Q formula (Hoffer, 1993) for eyes with an AL less than 22.0 mm and SRK/T formula (Retzlaff et al., 1990) for eyes with an AL of 22 mm or more. Visual acuity measurements were evaluated with logMAR charts for distance (6 m) and with Radner reading charts for near and intermediate vision (40 cm and 70 cm).

Patients were examined within 3 months postoperatively. A full ophthalmologic examination was performed as it was preoperatively with the main postoperative measurements, including binocular UDVA, UIVA, and UNVA. The binocular assessment was especially important in determining the performance of the combination of differing multifocal IOLs opposed to individual eyes.

A quality of vision (QoV) questionnaire was also completed postoperatively using a previously validated questionnaire (McAlinden et al., 2010). This assessed how bothered the patients were by the questioned symptoms and how often they required reading spectacles. For symptoms, the patients responded either not at all (0), a little (1), quite (2), or very (3). When asked about reading spectacles, the patients responded never (0), occasionally (1), quite often (2), or always (3). The previously developed QoV questionnaire uses a Rasch-tested linear scale; however, a Rasch conversion was not necessary in this case to define differences between each item. Instead, this study used standard categorical analysis techniques to determine statistical differences between each item between groups. In this way, fidelity of the quantitative data retained for each item rather than losing specificity via a Rasch conversion. In addition, a linear 0 to 10 scale was used to define each patient's subjective view of total quality of vision to gain a better understanding of his or her postoperative satisfaction.

**Intraocular Lenses**

The Lentis Mplus is a foldable biconvex 1-piece multifocal acrylic IOL. It has a refractive design and is rotationally asymmetric, containing an aspheric distance vision zone and a sector-shaped near vision segment to allow good transition between the zones. Light is reflected away from the optical axis when light hits the transition zone of the embedded segment, preventing superposition of interference or diffraction. This IOL is available in +1.50 D, +2.00 D, and +3.00 D adds. In this study, patients in Group 2 received a +3.00 D add (Lentis Mplus LS-312 MF30 IOL) and the patients in Group 3 received a C2.00 D add (Lentis Mplus LS-312 MF20) with the near add in the superotemporal position in the dominant eye.
The Lenstec SBL-3 is a biaspheric asymmetric refractive multifocal IOL. It is acrylic, contains a distance section combined with a near vision segment (C3.00 D) in the anterior optic separated by a small wedge-shaped transition zone, and has a neutral aberration profile, as described by Venter et al., (2014). All SBL-3 IOLs were placed with the near segment in the inferonasal position.

**Surgical Technique**

All surgeries were performed by the same experienced surgeon (J.E.M) with standard on-axis clear corneal phacoemulsification surgery. In all cases, the surgery was performed using sub-Tenon or topical anesthesia. A 2.75 mm incision was used to minimize residual corneal astigmatism, and the incision was placed on the steepest meridian to prevent the introduction of oblique astigmatism. Implantation of the multifocal IOL in the capsular bag was performed after a 5.0 mm anterior capsulorhexis was created. The refractive aim was emmetropia.

**Statistical Analysis**

Statistical analysis was performed using SPSS for Windows software (version 22, SPSS, Inc.) and Excel software (Microsoft Corp.). The Kolmogorov-Smirnov test was used to assess normality. For assessing continuous normal data, 1-way analysis of variance (ANOVA) with Tukey post hoc comparison was used. For assessing nonparametric data, the Kruskal-Wallis and Mann-Whitney *U* tests were applied. Following the methods outlined by Goodall et al., (2009) calculations showed that for this study to have 90% statistical power, the sample size required was more than 47 patients per group. The standard deviation of the QoV score was determined to be 0.90, and a clinically significant difference in QoV was determined to be 0.6. For all statistical analysis, the level of significance was a P value less than 0.05.

Results

<u>Demographics</u>

Table 1 shows the preoperative parameters in the 3 groups of patients. Each group comprised 60 patients (120 eyes).

Overall Satisfaction and Spectacle Independence

Figure 2 shows the overall QoV scores for which QoV was rated from 0 to 10, with 0, the worst and 10, the best. Group 3 displayed significantly better QoV scores than Group 1 ($P = .001$, ANOVA) and Group 2 ($P = .002$, ANOVA). There was no significant difference between Group 1 and Group 2 combined compared with Group 3.

Figure 3 shows the percentage frequency of responses to spectacle independence for Group 1 and Group 2 (combined) and Group 3. Ninety percent (108 of 120 patients) of Group 1 and Group 2 (combined) said they never wore spectacles or only required reading spectacles occasionally, which was comparable to results in Group 3 in which 93% (51 of 60 patients) said they never or occasionally needed reading spectacles.

Visual Disturbances and Photopic Phenomena

Table 2 shows the individual symptom responses found in each group. Group 3 had lower mean scores for each questioned symptom, except double vision. Group 3 was significantly less affected by blurred vision than Group 1 ($P = .005$, Mann-Whitney *U* test).

Visual Acuity and Refraction

Table 3 shows the objective visual outcomes. There were no significant differences in binocular visual acuity measures between the groups. Figure 4 shows the cumulative binocular UDVA, UIVA, and UNVA in each group. Figure 5 shows the safety in each group. Figure 6 shows the lines of difference between the postoperative UDVA and CDVA for the 3 groups.

There was no statistically significant difference in refractive sphere or the spherical equivalent (SE) between the groups; however, there was a statistically significant difference between the groups in postoperative refractive cylinder. Figure 7 shows the accuracy of the attempted SE correction in the 3 groups. Ninety-eight eyes (81.67%), 103 eyes (85.83%), and 103 eyes (85.83%) achieved within ± 0.50 D of emmetropia, and 119 eyes (99.17%), 119 eyes (99.17%), and 118 eyes (98.33%) achieved within ±1.00 D in Group 1, Group 2, and Group 3, respectively.

Figure 8 shows the postoperative refractive cylinder of the 3 groups.

**Discussion**

Asymmetric multifocal IOLs have improved the objective and subjective postoperative outcomes after IOL based surgery (Alió et al., 2012b; Ramón et al., 2012; Alió et al., 2011a; Venter et al., 2013; Montés-Micó et al., 2012). Because of the way the modern asymmetric multifocal IOL is designed, the position of the near segment and the power of the reading add can now be varied. These factors should be considered before multifocal IOL implantation; however, they have not been fully evaluated and might have an important influence on further enhancing postoperative patient satisfaction.

The manufacturers' guidelines indicate that the near segment of both rotationally asymmetric multifocal IOLs should be placed inferiorly with slight nasal deviation. An extensive study by Venter et al., (2013) with the near segment in the recommended inferonasal position found excellent postoperative visual performance with the Lentis Mplus multifocal IOL. However, incidental rotation of the near segment has been found to be well tolerated, leading de Wit et al., (2015) to evaluate this further. In their study, they found no significant difference in objective or

subjective postoperative outcomes between inferonasal placement and superotemporal placement, confirming that superotemporal placement is well tolerated and the outcomes are similar to those of the inferonasal placement recommended by the manufacturers.

However, our anecdotal evidence led us to evaluate this further. Our clinical experience showed us that superotemporal placement reduces dysphotopsias. A case report by Pazo et al., (2016) found that the superotemporal position of the near segment seems to increase the surface area of the distance zone exposed within the pupil, improving objective and subjective outcomes when placed this way in the dominant eye. The importance of this is evident when a patient enters an environment with bright lights; the good distance vision is retained despite pupil constriction because of the prevention of induced myopia, which can occur if too much of the near segment is in the pupillary region.

Another important consideration is the power of the reading segment selected. A study by McAlinden and Moore, (2011) found that asymmetric multifocal IOL implantation with a lower powered + 1.50 D near add in the dominant eye in conjunction with a +3.00 D near add in the nondominant eye provided a range of good binocular vision. The dominant eye had excellent distance and intermediate vision, and the fellow eye had excellent distance and near vision. Therefore, in this study, an asymmetric multifocal IOL with a lower powered near add (+2.00 D) was implanted with superotemporal placement in the dominant eye to reduce dysphotopic side effects and optimize distance visual acuity, in combination with a +3.00 D add placed inferonasally in the fellow nondominant eye.

The purpose of this study was to determine the effect on objective and subjective outcomes of this combined placement of near segments in comparison with bilateral inferonasal placement as advised by the manufacturers. To our knowledge, this is the first study to assess the objective and subjective postoperative outcomes of asymmetric multifocal IOLs positioned in this manner. This study provides surgeons with information regarding the placement of asymmetric multifocal IOLs as a way to improve postoperative patient satisfaction.

In our study, Group 1 and Group 2 had excellent overall QoV scores. There was no difference in mean scores between the groups. This is similar to a study of bilateral implantation of asymmetric multifocal IOLs with inferior placement of the near segment (Muñoz et al., 2011) in which patients were asked to rate their overall satisfaction postoperatively from 0 (least satisfied) to 10 (most satisfied). In that study, 78.1% of patients scored 8 or higher. Another study by Venter et al., (2014) in which bilateral SBL-3 IOLs were implanted inferonasally found that 75% of patients were very satisfied with the outcomes. However, in our study, Group 3 had a significantly better mean overall QoV score (8.93 ± 0.94 [SD]) than Group 1 (P = .001, ANOVA) and Group 2 (P = .002, ANOVA) despite no statistical difference in objective UDVA. This shows that patients with a combination of superotemporal near segment (+ 2.00 D) and an inferonasal near segment (+ 3.00 D) in the fellow eye seem to be significantly more content with their quality of vision within 3 months postoperatively.

All groups reported a low incidence of negative side effects. However, Group 3 was less affected by each of the questioned symptoms, except double vision, and Group 3 was significantly less affected by blurred vision than Group 1; there was no statistically significant difference in blurred vision between Group 2 and Group 3.

In addition, the level of safety was high in all groups, with no patient losing 2 or more lines of CDVA. Also, accuracy of the intended SE correction was excellent in all groups. There were no significant differences between the 3 groups in binocular UDVA, UIVA, and UNVA within 3 months postoperatively; however, there was a significant difference between the overall quality of vision. Therefore, this study suggests that the benefits of superotemporal placement of the near segment (+ 2.00 D) in the dominant eye improves the subjective perception of quality of vision and an individual still maintains adequate near and intermediate vision through inferonasal placement of a + 3.00 D add asymmetric multifocal IOL. There was a statistically significant difference in postoperative cylinder between the groups; however, it was not clinically relevant. To confirm this, we excluded patients with a postoperative cylinder of more than 0.50 D in each group and reassessed the overall quality of vision between the groups. The combined superotemporal and inferonasal placement still yielded a statistically significantly higher overall QoV score.

Further analysis of this combination of asymmetric multifocal IOLs is required in a study with longer postoperative follow-up to determine how neuroadaptation affects subjective and objective outcomes and whether the superotemporal and inferonasal placement of asymmetric multifocal IOLs still results in better quality of vision over longer postoperative follow-ups.

One limitation of this study is that all of the different IOL combinations were not assessed (eg, another group with a +2.00 D near add positioned inferonasally in the dominant eye in combination with inferonasal placement of a +3.00 D near add in the fellow eye). McAlinden and Moore, (2011) assessed the use of a +1.50 D add inferonasally in the dominant eye. Therefore, future studies will assess the effect of other combinations of asymmetric multifocal IOLs on the objective and subjective outcomes to provide surgeons with more complete information on the best combination of IOL position and power. However, this study did find that the combination of superotemporal placement (+2.00 D) in the dominant eye and inferonasal placement (+3.00 D) in the nondominant eye provided binocular uncorrected visual acuity similar to that achieved with bilateral inferonasal placement, which was recommended by the manufacturers. In addition, the better level of quality of vision, despite no statistically significant difference between the groups in objective visual outcomes, suggests that this combination of asymmetric multifocal IOLs might enhance a patient's acceptance of the postoperative outcomes.

In conclusion, this study found that superotemporal placement of the near segment of a lower add (+2.00 D) asymmetric multifocal IOL in the dominant eye combined with a higher add (+3.00 D) and inferonasal near segment placement in the nondominant eye provided excellent overall quality of vision without affecting objective visual performance.

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**FIGURES & TABLES**

**Figure 1 -** Clinical retroillumination images of (top) superotemporal position in a right eye and (bottom) inferonasal position in a left eye of the near segment of rotationally asymmetric multifocal IOLs in the eye.

**Figure 2 -** The mean overall QoV scores in the 3 groups within 3 months postoperatively. The QoV was rated out of 10, with 0 being the worst and 10 being the best (QoV = quality of vision).

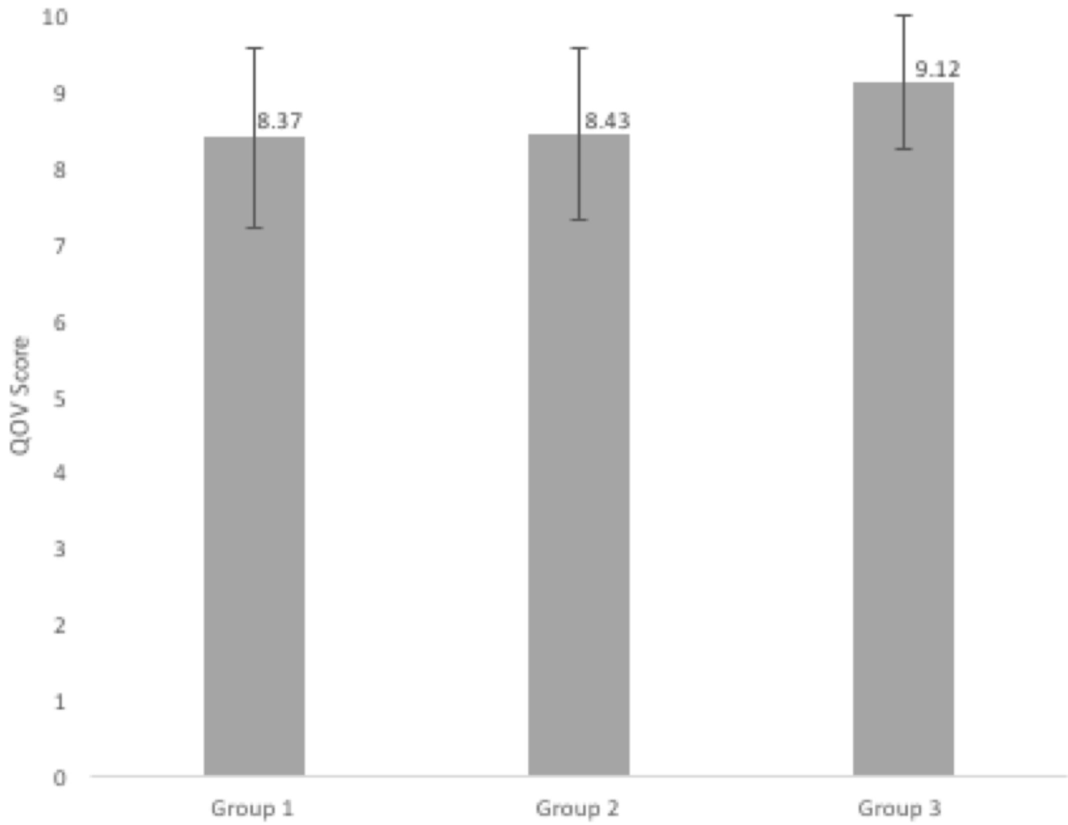


**Figure 3 -** Patient response to how often they wear reading spectacles. The percentage of responses within 3months postoperatively in Group 1 and Group 2 combined and Group 3 are shown in the histogram.

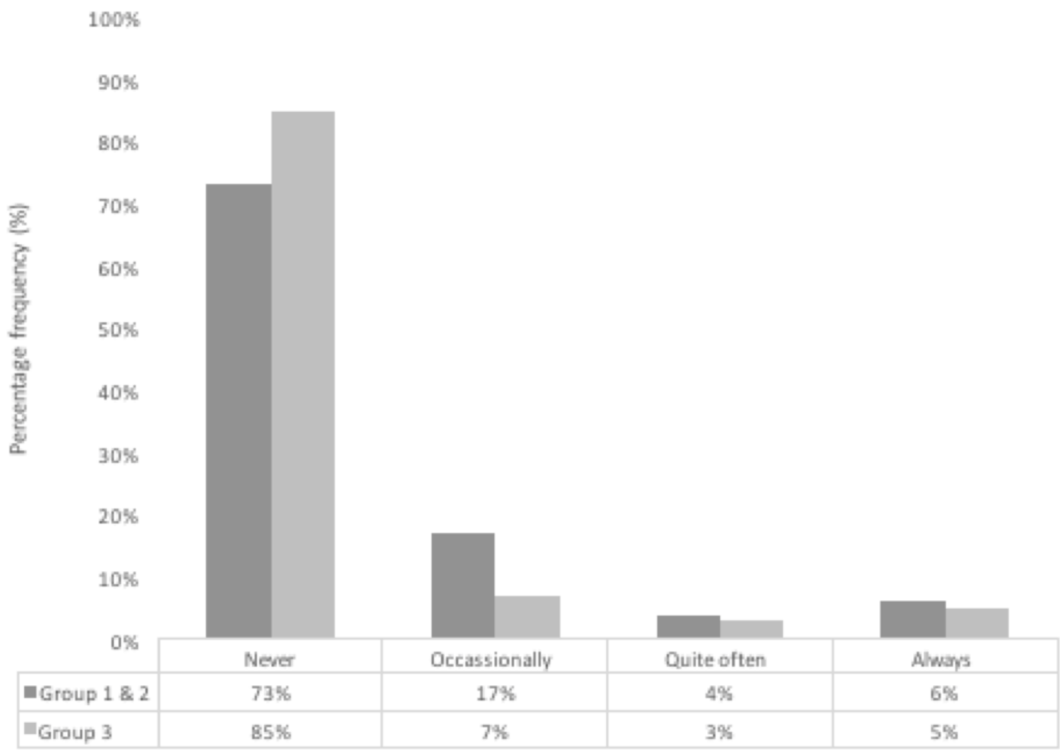
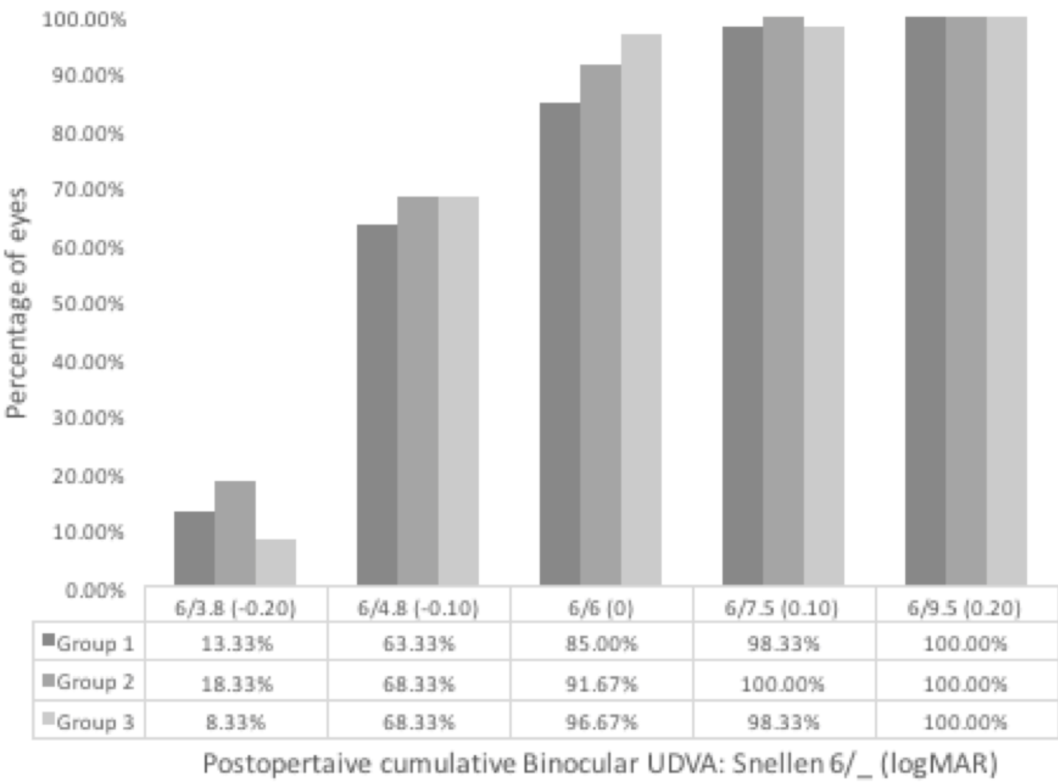
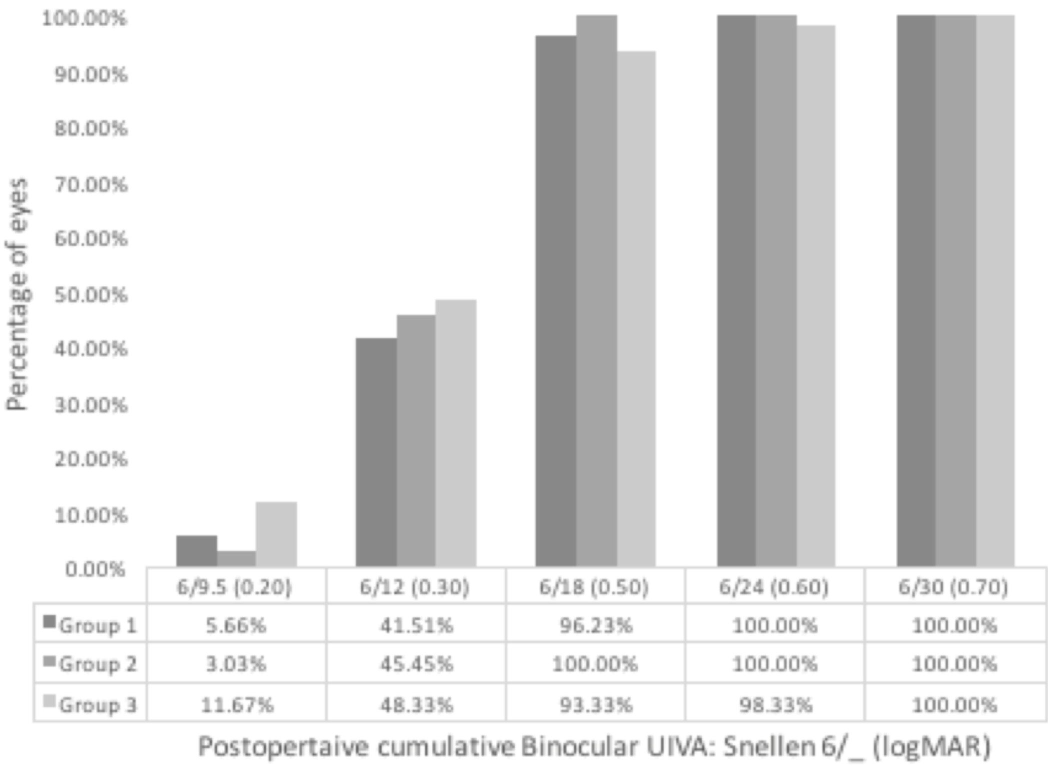


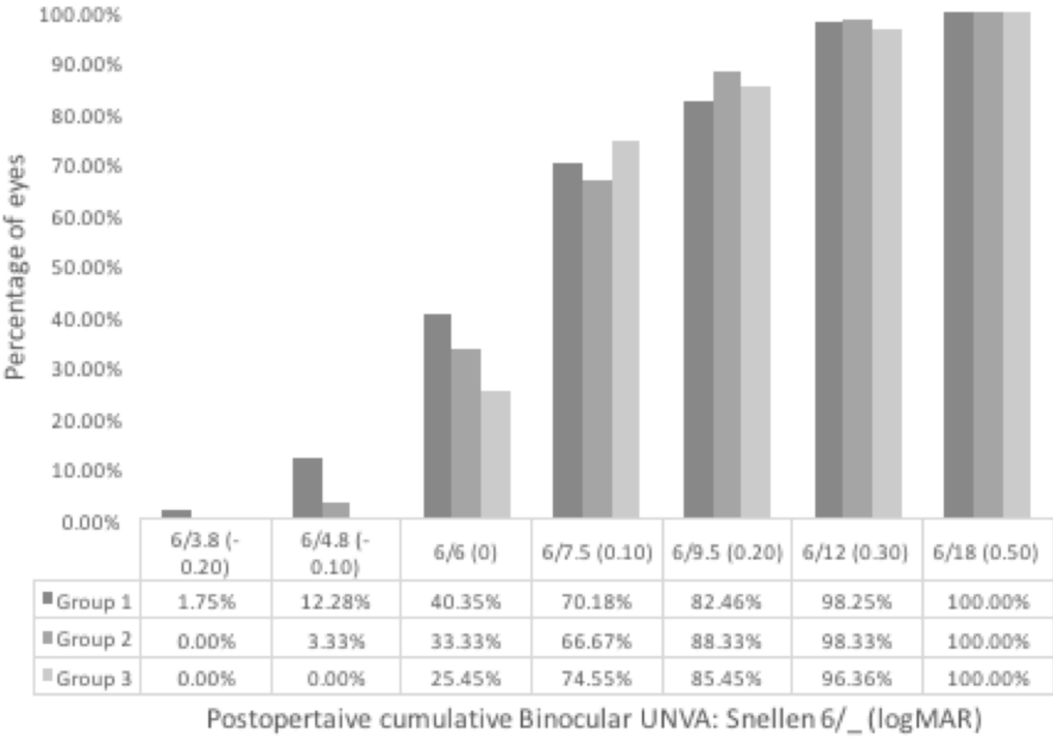
**Figure 4 -** Cumulative binocular uncorrected (A) distance, (B) intermediate, and (C) near visual acuity in the 3 groups 3 months postoperatively (UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity).




**A**

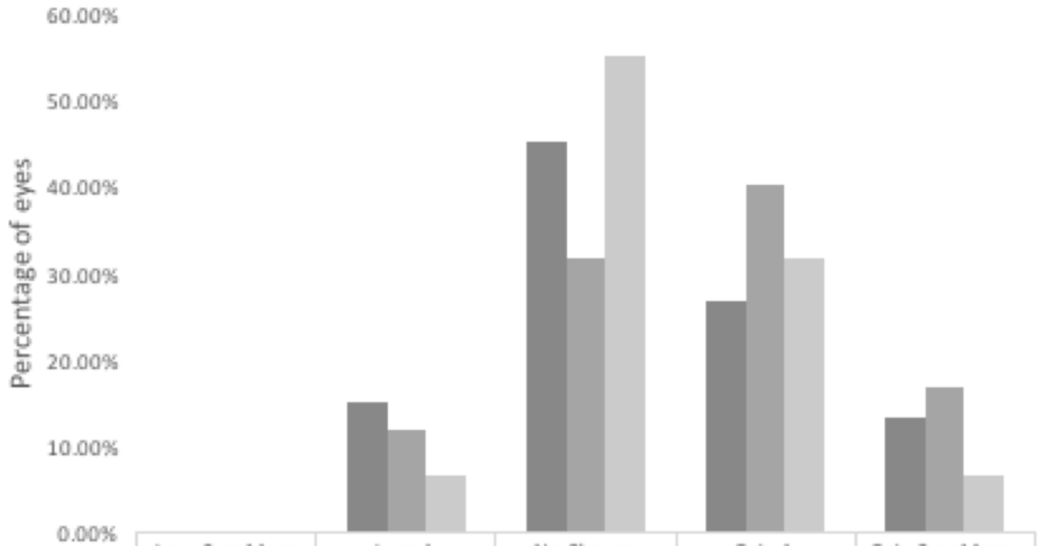

Percentage of eyes
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
6/9.5 (0.20)
6/12 (0.30)
6/18 (0.50)
6/24 (0.60)
6/30 (0.70)
Group 1 5.66% 41.51% 96.23% 100.00% 100.00%
Group 2 3.03% 45.45% 100.00% 100.00% 100.00%
Group 3 11.67% 48.33% 93.33% 98.33% 100.00%
Postopertaive cumulative Binocular UIVA: Snellen 6/_ (logMAR)

**B**


Percentage of eyes
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
6/3.8 (-0.20)
6/4.8 (-0.10)
6/6 (0)
6/7.5 (0.10)
6/9.5 (0.20)
6/12 (0.30)
6/18 (0.50)
Group 1 1.75% 12.28% 40.35% 70.18% 82.46% 98.25% 100.00%
Group 2 0.00% 3.33% 33.33% 66.67% 88.33% 98.33% 100.00%
Group 3 0.00% 0.00% 25.45% 74.55% 85.45% 96.36% 100.00%
Postopertaive cumulative Binocular UNVA: Snellen 6/_ (logMAR)

**C**

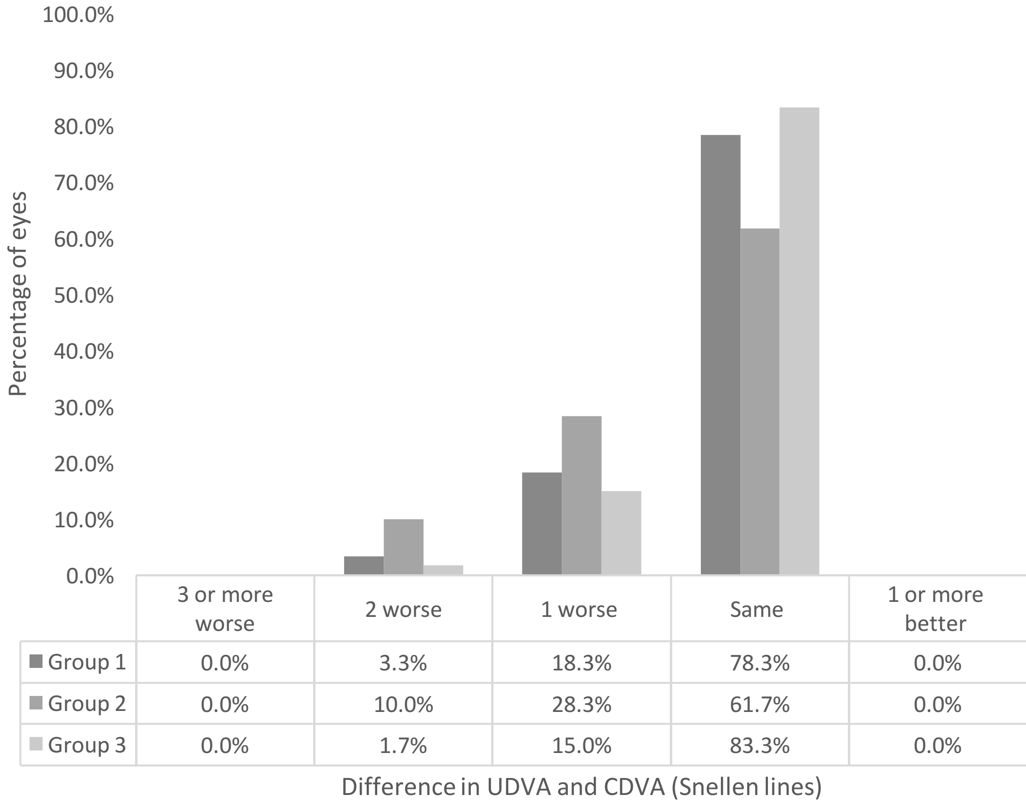
**Figure 5 -** Safety comparison of preoperative CDVA and postoperative binocular CDVA in the 3 groups 3 months postoperatively (CDVA = corrected distance visual acuity).




| | Loss 2 or More | Loss 1 | No Change | Gain 1 | Gain 2 or More |
|---|---|---|---|---|---|
| Group 1 | 0.00% | 15.00% | 45.00% | 26.67% | 13.33% |
| Group 2 | 0.00% | 11.67% | 31.67% | 40.00% | 16.67% |
| Group 3 | 0.00% | 6.67% | 55.00% | 31.67% | 6.67% |

Lines Change in CDVA

**Figure 6 -** Efficacy comparison of binocular postoperative UDVA and CDVA in the 3 groups 3 months. (CDVA = corrected distance visual acuity).




| | 3 or more worse | 2 worse | 1 worse | Same | 1 or more better |
|---|---|---|---|---|---|
| Group 1 | 0.0% | 3.3% | 18.3% | 78.3% | 0.0% |
| Group 2 | 0.0% | 10.0% | 28.3% | 61.7% | 0.0% |
| Group 3 | 0.0% | 1.7% | 15.0% | 83.3% | 0.0% |

**Figure 7 -** The accuracy of the intended SE refraction in the 3 groups 3 months postoperatively (SE = spherical equivalent).

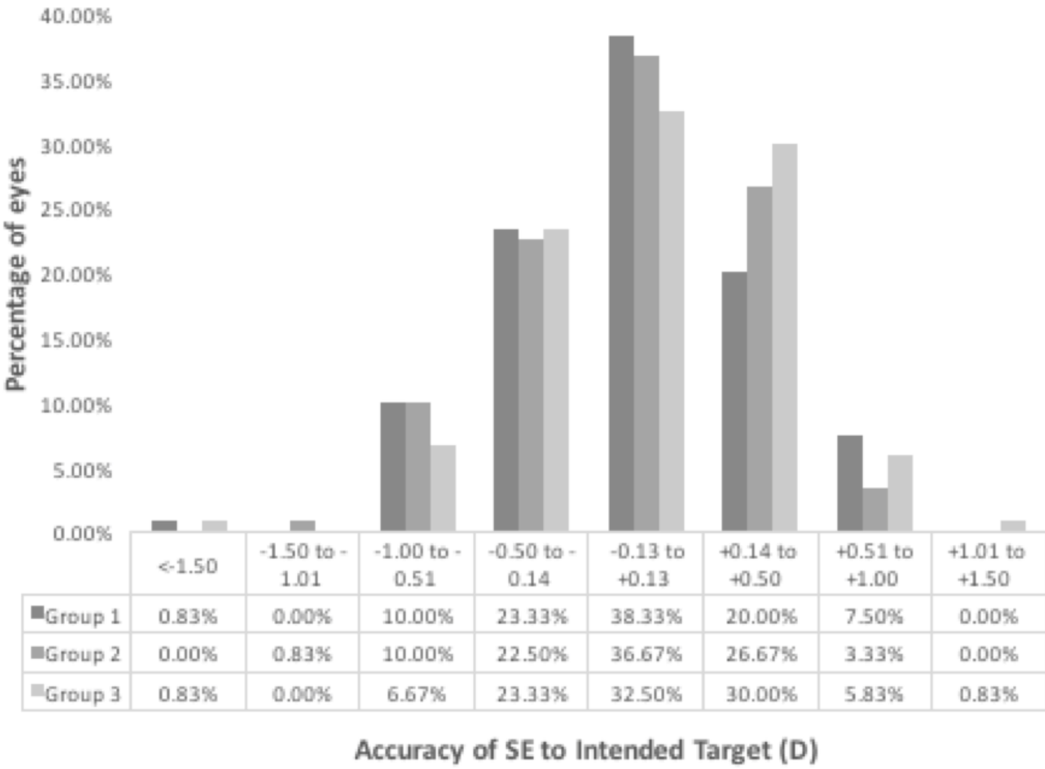
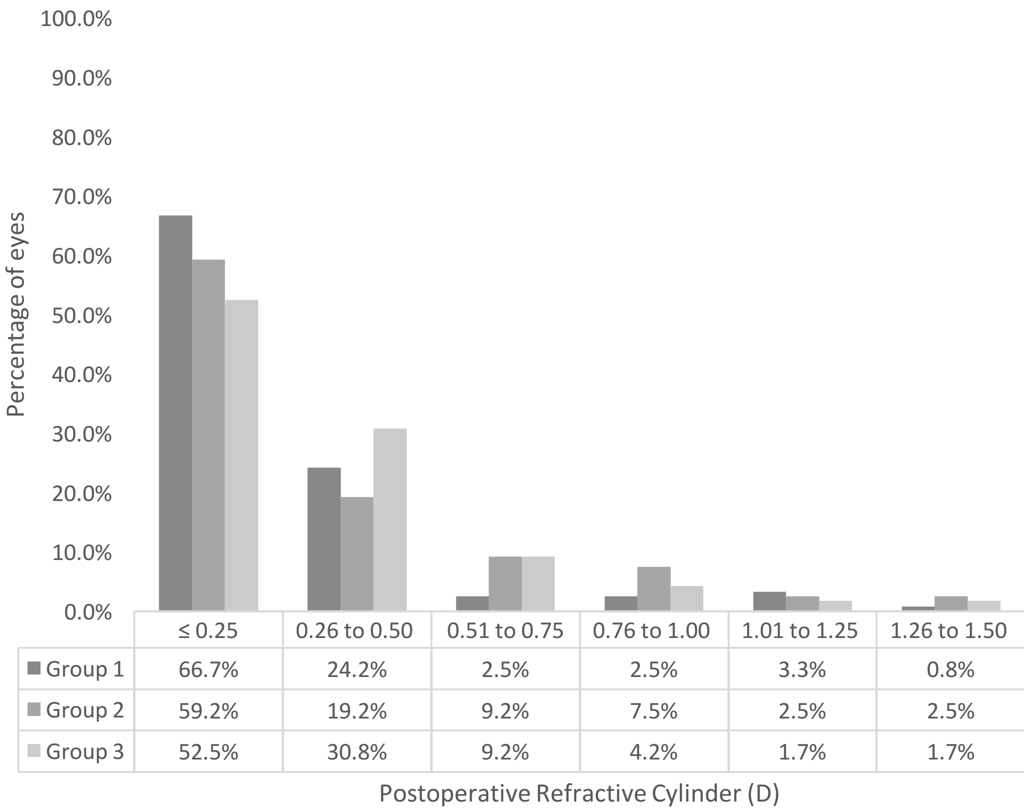


**Figure 8 -** Histogram of postoperative refractive cylinder in the 3 groups.




| | ≤ 0.25 | 0.26 to 0.50 | 0.51 to 0.75 | 0.76 to 1.00 | 1.01 to 1.25 | 1.26 to 1.50 |
|---|---|---|---|---|---|---|
| Group 1 | 66.7% | 24.2% | 2.5% | 2.5% | 3.3% | 0.8% |
| Group 2 | 59.2% | 19.2% | 9.2% | 7.5% | 2.5% | 2.5% |
| Group 3 | 52.5% | 30.8% | 9.2% | 4.2% | 1.7% | 1.7% |

**Table 1 -** Between-group comparison of preoperative patient data.

| | Group 1 | Group 2 | Group 3 | P Value |
|---|---|---|---|---|
| **Patients** | 60 | 60 | 60 | |
| **Eyes** | 120 | 120 | 120 | |
| **Male, n (%)** | 16 (27) | 28 (47) | 18 (30) | |
| **Female, n (%)** | 44 (73) | 32 (53) | 42 (70) | |
| **Age (y)** | | | | |
| Mean ± SD | 59.43 ± 8.14 | 63.50 ± 9.30 | 58.65 ± 6.23 | 0.002 |
| Median | 60 | 66 | 56 | |
| Range | 47, 73 | 51, 88 | 46, 70 | |
| **Sphere (D)** | | | | |
| Mean ± SD | 1.31 ± 3.11 | 0.75 ± 5.12 | 0.50 ± 3.59 | 0.285 |
| Median | 1.50 | 2.00 | 1.50 | |
| Range | -10.75, 8.75 | -16.50, 8.00 | -10.75, 6.50 | |
| **Cylinder (D)** | | | | |
| Mean ± SD | -0.54 ± 0.53 | -0.75 ± 0.61 | -0.52 ± 0.46 | 0.002 |
| Median | -0.50 | -0.75 | -0.50 | |
| Range | -2.25, 0 | -2.50, 0 | -2.00, 0 | |
| **LogMAR CDVA** | | | | |
| Mean ± SD | -0.05 ± 0.12 | -0.02 ± 0.10 | -0.03 ± 0.11 | 0.261 |
| Median | -0.10 | 0 | -0.10 | |
| Range | -0.20, 0.32 | -0.20, 0.30 | -0.10, 0.30 | |
| *SD = standard deviation, D = Dioptres, CDVA = corrected distance visual acuity* | | | | |

**Table 2 -** Between-group comparison of subjective responses 3 months postoperatively.

| | Group 1 | Group 2 | Group 3 | P value |
|---|---|---|---|---|
| **How much does glare bother you?** | 0.58 ± 0.85 | 0.50 ± 0.72 | 0.30 ± 0.65 | 0.78 |
| **How much do the haloes bother you?** | 0.43 ± 0.85 | 0.43 ± 0.72 | 0.17 ± 0.42 | 0.557 |
| **How much do the starbursts bother you?** | 0.63 ± 0.90 | 0.75 ± 0.86 | 0.25 ± 0.60 | 0.286 |
| **How much does hazy vision bother you?** | 0.38 ± 0.69 | 0.33 ± 0.57 | 0.13 ± 0.43 | 0.835 |
| **How much does blurred vision bother you?** | 0.58 ± 0.83 | 0.27 ± 0.52 | 0.23 ± 0.53 | 0.023 |
| **How much does distortion bother you?** | 0.05 ± 0.39 | 0.10 ± 0.35 | 0 | 0.253 |
| **How much do double images bother you?** | 0.08 ± 0.33 | 0.20 ± 0.55 | 0.22 ± 0.58 | 0.211 |
| *Grading scale: 0 = Not at all; 1 = A little; 2 = Quite; 3 = Very* | | | | |

**Table 3 -** Between-group comparison of visual and refractive outcomes 3 months postoperatively.

| | Group 1 | Group 2 | Group 3 | P value |
|---|---|---|---|---|
| **Binocular logMAR UDVA** | | | | |
| Mean ± SD | -0.05 ± 0.10 | -0.08 ± 0.08 | -0.07 ± 0.07 | 0.195 |
| Median | -0.08 | -0.10 | -0.1 | |
| Range | -0.20, 0.20 | -0.22, 0.10 | -0.20, 0.24 | |
| **Sphere (D)** | | | | |
| Mean ± SD | 0.14 ± 0.47 | 0.07 ± 0.37 | 0.20 ± 0.44 | 0.056 |
| Median | 0 | 0 | 0.13 | |
| Range | -1.25, 1.25 | -0.75, 1.25 | -1.25, 1.75 | |
| **Cylinder (D)** | | | | |
| Mean ± SD | -0.33 ± 0.40 | -0.23 ± 0.35 | -0.36 ± 0.34 | 0.014 |
| Median | -0.25 | 0 | -0.25 | |
| Range | -1.50, 0 | -1.50, 0 | -1.50, 0 | |
| **SE (D)** | | | | |
| Mean ± SD | -0.03 ± 0.47 | -0.05 ± 0.41 | 0.02 ± 0.43 | 0.457 |
| Median | 0 | 0 | 0 | |
| Range | -1.63, 1.00 | -1.13, 1.00 | -1.63, 1.63 | |
| **Binocular LogMAR CDVA** | | | | |
| Mean ± SD | -0.11 ± 0.07 | -0.10 ± 0.07 | -0.09 ± 0.06 | 0.525 |
| Median | -0.10 | -0.10 | -0.10 | |
| Range | -0.20, 0.10 | -0.22, 0.10 | -0.20, 0.20 | |
| **Binocular UNVA (LogMAR)** | | | | |
| Mean ± SD | 0.10 ± 0.14 | 0.11 ± 0.11 | 0.12 ± 0.11 | 0.622 |
| Median | 0.10 | 0.10 | 0.10 | |
| Range | -0.20, 0.50 | -0.10, 0.40 | 0, 0.40 | |
| **Binocular UIVA (LogMAR)** | | | | |
| Mean ± SD | 0.38 ± 0.10 | 0.36 ± 0.07 | 0.38 ± 0.12 | 0.742 |
| Median | 0.40 | 0.40 | 0.40 | |
| Range | 0.20, 0.60 | 0.20, 0.50 | 0.20, 0.70 | |
| **Binocular DCNVA (LogMAR)** | | | | |
| Mean ± SD | 0.11 ± 0.18 | 0.11 ± 0.10 | 0.13 ± 0.13 | 0.721 |
| Median | 0 | 0.10 | 0.10 | |
| Range | -0.10, 0.60 | -0.10, 0.30 | 0, 0.50 | |
| **Binocular DCIVA (LogMAR)** | | | | |
| Mean ± SD | 0.31 ± 0.12 | 0.35 ± 0.07 | 0.34 ± 0.10 | 0.275 |
| Median | 0.30 | 0.35 | 0.30 | |
| Range | -0.10, 0.50 | 0.20, 0.50 | 0.20, 0.60 | |

*UDVA = unaided distance visual acuity, SD = standard deviation , D = Dioptres,* SE = spherical equivalent*, CDVA = corrected distance visual acuity, UNVA = unaided near visual acuity*, *UIVA = unaided intermediate visual acuity, DCNVA = distance corrected near visual acuity, DCIVA = distance corrected intermediate visual acuity*

# 8. CONCLUSIONS

Richard N. McNeely

## Contribution

Richard N. McNeely carried out all research unless otherwise stated

## 8.1 General discussion

Subjective assessment of visual function through questionnaires is now an essential aspect of clinical assessment for ophthalmic treatments and interventions, and a range of formal questionnaires have subsequently been developed and introduced into the clinical setting. It is essential that questionnaires are developed properly to ensure they accurately measure what they are designed to measure. An accurate validation method is required to ensure all items within the questionnaire contribute to the measured visual trait.

Cataract surgery is a very common procedure and nowadays has a high level of predictability, efficacy and safety (Quintana et al., 2009). Assessment of visual acuity is one of the main measures for cataract surgery outcomes however the full impact of cataract surgery is only truly determined through a subjective questionnaire (McAlinden et al., 2011a). Many ophthalmic questionnaires have now been developed and these questionnaires often require the patient to answer a variety of questions through selection of an ordinal response that reflects their subjective opinion. For example, the 14-item visual functioning index (VF-14) (Steinberg et al., 1994) uses a difficulty rating from 0 (no difficulty) to 4 (unable to do). Prior to the introduction of item response theory (IRT), primarily Rasch analysis, classical test theory (CTT) was utilised where the response categories are numbered and a simple score is summed across the questionnaire, and the number is then considered to represent the visual trait under investigation. However, various studies have now outlined the drawbacks with this methodology (Massof, 2002; Wright and Linacre, 1989). This method of summary scoring assumes that each item within the questionnaire is of equal difficulty and that the difficulty step between each ordinal response is equal. Therefore, the scaling cannot be assumed to be additive and linearly related to the visual trait that the questionnaire is assessing (McAlinden et al., 2010; Pesudovs, 2006). Therefore, the production of subjective questionnaires was changed to provide a more accurate development method. As outlined in this thesis, currently the predominant method for development is Rasch analysis which is a psychometric model that presents a probabilistic relationship between person ability and item difficulty and therefore allows items to be arranged from the easiest to hardest, assuming the unidimensionality of the latent trait, and provides the transformation of raw ordinal scores into a linear interval scale (McAlinden et al., 2011b). This method is now widely accepted in ophthalmology and indeed Rasch analysis has been used to reassess various older ophthalmic questionnaires that were developed with CTT (Pesudovs et al., 2008; Lamoureux et al., 2008). The use of ophthalmic questionnaires has increased and is now widely accepted as an essential aspect of clinical assessment and in many cases is a requirement in clinical trials (Pesudovs et al., 2007). A subjective questionnaire to determine quality of vision (QoV) has been introduced because it is recognised that a patient may have a good level of visual acuity however when objectively tested they may perceive their QoV very differently (McAlinden et al., 2010). This QoV questionnaire has been used widely in refractive surgery and cataract surgery.

Therefore, this thesis sought to investigate the use of Rasch analysis in the assessment of a QoV questionnaire (McAlinden et al., 2010) and to outline an alternative application of Rasch analysis to enable adequate use of ophthalmic questionnaires. I also sought to outline the importance of preoperative subcategorisation of patients prior to using a revised QoV questionnaire.

Additionally, this thesis sought to assess the objective and subjective outcomes of rotationally asymmetric multifocal IOLs to inform clinicians of their postoperative performance.

### 8.1.1 Subjective questionnaires

The use of Rasch analysis is now widely established as the appropriate method for development of ophthalmic questionnaires, and has been used to dismiss previously developed questionnaires. Rasch analysis was originally used in the educational setting for intelligence and attainment tests. The tests consisted of items where the answers were known and there was an expected pattern of responses. The Rasch model is based on a probabilistic relationship between person ability and item difficulty with items ordered from the easiest to the hardest. This is dependent on the frequency of correct answers with easier items answered correctly more often and correct answers to harder questions provided less frequently. This concept has been used in the development of vision-related questionnaires. The Rasch model is based on the fundamental assumption of specific objectivity, as outlined in paper I, which assumes the homogeneity of both the test items and the population of interest. However, as outlined the answers to the items in the educational setting are known but with vision-related questionnaires the responses are subjective and therefore the answers are not known. For example, if a patient answered just the easiest and hardest items, dependent on the Rasch item ordering, this would represent an outlier because if a patient answers the hardest item they should be able to answer all the easier items. However, vision-related questionnaire items which misfit the model cannot simply be discarded, as is the current practice, because this is not just an outlier because there are no right or wrong answers and this provides vital information on the trait under investigation for this patient. Additionally, the items may function differently and patients may respond differently to the items because the trait under investigation is subjective and may be influenced by different patient groups or the time they are completed, and subsequently affect the fit to the Rasch model. Therefore, this gave the premise to my first paper where I sought to investigate the use of Rasch analysis with a QoV questionnaires at two separate postoperative assessments. To do this I applied Rasch analysis to the questionnaire data, using the approach followed in various studies (Finger et al., 2012; Gothwal et al., 2009; Gothwal et al., 2010; McAlinden et al., 2011b; Huang et al., 2017; Khadka et al., 2011) which uses misfit statistics of the items and the items characteristics curves (ICCs), and this was performed at two postoperative assessments. This research highlighted that the questionnaire data found with the QoV questionnaire fitted the Rasch model and was therefore "Rasch-valid" at 1-month, however at the second postoperative assessment (12 months) with the same cohort of patients the questionnaire was "Rasch-invalid". Additionally, with the ICCs the ordinal response of "quite" was expressed in most of the items 1-month postoperatively, however at 12 months the response "quite" was no longer expressed. In line with the current advocated approach the questionnaire at 12 months should be discarded despite being "Rasch-valid" 11 months earlier. This highlights the shortcomings of Rasch analysis and brings into question the validity of using Rasch analysis to develop vision-related questionnaires. However, the paper also outlined that rather than disregarding the use of Rasch analysis altogether in ophthalmic questionnaires it can be utilised in an alternative way to provide insights into the population under investigation and highlight patients that are significantly annoyed by particular symptoms. At the population level the alternative approach can be used to investigate the prevalence of symptoms across a population allowing better characterisation of patient groups preoperatively and an appropriate follow-up postoperatively, in order to assess the effectiveness of treatments. Furthermore, at the individual level the new approach can highlight patients that are significantly annoyed by particular symptoms and may require additional care. This new stratified approach will allow more adequate application of Rasch analysis within the context of ophthalmic questionnaires, so that insights gained from the analysis can be exploited to enhance the quality of care and patient care experience.

To date Rasch analysis has been used to develop new ophthalmic questionnaires and reevaluate or dismiss existing ophthalmic questionnaires. A study by Pesudovs et al., (2003) reevaluated an ophthalmic questionnaire and utilised Rasch analysis to assess targeting of the instrument to the patients under investigation and internal consistency. They reported inadequacies with the questionnaire and that additional questions were required to fulfill the requirements for patients with superior ability. This analysis and conclusion was achieved by the Rasch model and fit statistics, where an item is deemed not to contribute to the overall scale if a high item infit or outfit is determined. Various studies use the Rasch model fit statistics to discard items within the questionnaire (Pesudovs et al., 2009; Finger et al., 2012). However, as outlined in paper I this is often concluded from a single and potentially non-representative cohort of patients. Pesudovs et al., (2003), as discussed above, only recruited 43 patients into their study and at one time point. However, paper I in this thesis outlines the shortcomings of this methodology. The Rasch model requires constant monitoring (Wright and Stone, 1999) and it appears cannot be used to approve or discard an ophthalmic questionnaire on a single population at one postoperative assessment.

QoV is now an important measurement following refractive lens exchange (RLE) and cataract extraction surgery with subsequent implantation of a multifocal IOL because it is considered that this intervention will have an impact on how an individual perceives their vision (McAlinden et al., 2010). Therefore, it is important that questionnaires are used appropriately and accurately to allow comparison of treatments. As discussed, the method used to develop questionnaires is essential to provide a meaningful clinical measurement that gives the clinician valuable information about their patient, but also allows accurate comparison between different treatments and interventions. As outlined in paper I the use of an alternative application of the Rasch model can be used at both the population and individual level. Therefore, in paper II of this thesis I utilised this alternative approach to asses if the prevalence of symptoms at the population level of a QoV questionnaire were affected by a patient's lifestyle demands. This approach was used to highlight the item ordering and misfit statistics of different lifestyle groups; frequent or infrequent drivers, and patients with frequent or infrequent close work demands. In this study, it was found that the item ordering and misfit statistics of the same questionnaire were different between the different lifestyle groups. To assess this further the relationship between the subjective visual symptom items and the objective clinical tests were assessed. Initially, the correlation between objective clinical tests and subjective ordinal responses were assessed for the overall cohort and it was found that there with patients who reported to be more affected subjectively showing a reduced objective performance with corresponding objective clinical tests. This correlation was used to further corroborate the difference between frequent and infrequent drivers, and it was found that the correlation between objective and subjective tests with the two separate lifestyle groups differed. This further supported the difference found by the varying Rasch characteristics and outlined that frequent and infrequent drivers respond differently to the QoV questionnaire. Currently, Rasch analysis is used on a single cohort of patients and conclusions are made regarding subjective outcomes from questionnaires depending on the item ordering and misfit. However, this study highlighted that different patient groups report different subjective responses, however the current methodology does not attempt to subcategorise preoperative groups. The current methodology gives each patient a score on a Rasch converted scale however it does not assess if the Rasch scale is the same for all patient groups which will therefore affect the accuracy of comparisons between subjective outcomes. This paper highlighted the importance of preoperative subcategorisation of groups with the same item ordering to allow similar groups to be assessed and subsequently improve the use of a QoV questionnaire, or other ophthalmic questionnaires. Rasch analysis without preoperative grouping on item ordering assumes that the whole cohort of patients perceives their QoV the same, however it is clear that QoV is affected by different lifestyles and this should be considered when comparing different IOLs and treatments.

This research regarding questionnaires outlines the importance of subjective assessment, however the current most advocated approach for questionnaire development has its shortcomings. An alternative application of Rasch analysis as a decision support tool is therefore outlined to help assess patients at a population and individual level. Furthermore, the use of subcategorisation of patients preoperatively is important when assessing QoV.

### 8.1.2 Asymmetric multifocal IOLs

Rotationally asymmetric multifocal IOLs have been used for the last 8 years. Various studies have outlined the early postoperative outcomes of the first commercially available rotationally asymmetric multifocal IOL. The Lentis Mplus IOL has been found to provide excellent distance and near visual acuity with a high satisfaction rate (Venter et al., 2013). To my knowledge there is only one study outlining the early postoperative outcomes of the Lenstec SBL-3 IOL which is the second commercially available asymmetric multifocal IOL (Venter et al., 2014). The study by Venter et al., (2014) only outlined the outcomes of the SBL-3 IOL up to 3 months postoperatively, therefore, paper III of this thesis sought to assess the outcomes of this IOL at 3 months and 12 months postoperatively to determine if there were any significant changes between the two assessments. Additionally, to my knowledge there are no studies of the Mplus IOL up to 12 months postoperatively, therefore paper IV sought to compare the two commercially available IOLs at 12 months, which would allow for neuroadaptation to occur.

My research further informs clinicians of the performance of rotationally asymmetric multifocal IOLs. Paper III outlines the SBL-3 IOL where it was found that the IOL provides an excellent level of unaided visual acuity similar to that found in the initial study (Venter et al., 2014). The visual objective outcomes displayed no significant difference between the 3-month and 12-month postoperative time periods. However, there was a significant improvement in subjective QoV outcomes between the two postoperative assessments. The individual visual symptom items within the QoV questionnaire and the overall 0-10 score were used to assess subjective QoV. Patients reported to be significantly less affected by blurred vision 12 months postoperatively when the subjective responses to this visual symptom item within the questionnaire were compared. Additionally, the overall linear 0-10 score designed to indicate overall QoV significantly improved between the two postoperative assessments. This significant improvement in overall QoV at 12 months led us to compare the objective and subjective performance of the two commercially available asymmetric multifocal IOLs at this 12-month postoperative interval. This allowed for neuroadaptation to occur and a direct comparison of the two available asymmetric multifocal IOLs following this neuroadaptation period, which has not been previously performed. Paper IV highlighted that there was no significant difference between the overall QoV scores and the separate visual symptom items within the questionnaire between the two IOLs. The overall satisfaction was superior to that found in another asymmetric multifocal IOL study (Muñoz et al., 2011). A significant difference in binocular unaided near visual acuity (UNVA) and binocular distance corrected near visual acuity (DCNVA) was observed with a superior performance found with the SBL-3 IOL. This was also reflected in the subjective responses for the requirement of reading glasses with more patients reporting to never require reading glasses.

Paper III and IV outline excellent objective visual and subjective postoperative outcomes as previously described (Venter et al., 2013; Venter et al., 2014), however this research informs the surgeon of the performance of both multifocal IOLs up to 12 months postoperatively. Both IOLs provide excellent visual acuity and overall

QoV, however it appears that the SBL-3 IOL provides superior UNVA and may be more appropriate to implant in a patient with high near visual demands.

One of the main causes of dissatisfaction following symmetric multifocal IOL implantation is blurred vision which is usually caused by residual ametropia and / or astigmatism (Woodward et al., 2009; de Vries et al., 2011). Therefore, this research also sought to determine the impact of residual astigmatism on postoperative subjective outcomes following asymmetric multifocal IOL implantation. Hayashi et al., (2010) found that an increasing magnitude of astigmatism significantly reduced UDVA with symmetric multifocal IOLs and the same was found in paper V. However, in my research it was found that asymmetric multifocal IOLs subjectively tolerated increasing magnitudes of residual refractive or corneal astigmatism.

This research informs clinicians of the impact of residual astigmatism on asymmetric multifocal IOLs and aids clinical management of residual astigmatism with these IOLs.

### 8.1.3 Important preoperative considerations

Rotationally asymmetric multifocal IOLs consists of a distance zone and a near zone and can be placed in various rotational positions. This contrasts with the symmetric multifocal IOL design which consists of concentric rings where the rotational position does not affect the performance of the IOL. The manufacturers recommend inferior placement of the near segment with slight nasal deviation, however it has been found that the near segment can be placed in different rotational positions without affecting the objective and subjective performance of the IOL (de

Wit et al., 2015). Additionally, the near segments of asymmetric multifocal IOLs are available in different powers, and it has been shown that the lower power (+2.00 dioptre (D)) provides good intermediate vision however the near vision is reduced (Alió et al., 2011). Additionally, a combination of a lower addition (add) in one eye with a higher add in the fellow eye provides a high quality of life (QoL) (McAlinden and Moore, 2011). It is evident that a variation from the normal placement of near segments and a combination of different near additions is well tolerated and provides good postoperative outcomes, however this has not yet been fully investigated. Therefore, the final paper in my research sought to investigate this further. This paper compared the objective and subjective outcomes of patients implanted with the near add placed superotemporally in the dominant eye combined with inferonasal placement in the nondominant eye to patients with bilateral inferonasal implantation of the near segment. Patients with a combination of superotemporal and inferonasal placement received a lower add in the dominant eye (+2.00 D) with a higher power in the nondominant eye (+3.00 D). Patients in the bilateral inferonasal groups received high power additions (+3.00 D) in each eye. The group with a combination of superotemporal and inferonasal placement showed significantly superior QoV to bilateral inferonasal placement despite no significant difference in objective visual and refractive outcomes.

Optimising the objective and subjective outcomes is very important, and I found that superotemporal placement, with a lower add, in combination with an inferonasal placement provides an excellent subjective postoperative outcome. However, this study was performed 3 months postoperatively and it would be beneficial to assess the outcomes at a longer postoperative time.

## 8.2 Future work

Initial work to follow on from the research reported here will continue to explore the optimisation of QoV following multifocal IOL implantation. The work will continue to assess the factors that influence the postoperative subjective outcomes following asymmetric multifocal IOL implantation. To follow on from my research regarding the use of different rotational positions of the near segment and different near add powers further comparisons between all possible combinations is required. It would be beneficial to know the objective and subjective performance achieved from inferonasal placement with a +2.00 D add in the dominant eye combined with inferonasal placement of a +3.00 D add in the fellow nondominant. Additionally, this combination of IOL implantation should be compared to the placement performed in paper VI and bilateral inferonasal placement (+3.00 D). In my future work I will also determine the impact of inserting bilateral asymmetric multifocal IOLs with a +2.00 D add in each eye but target myopia in the nondominant eye to give the required near vision, because it has been found that a +2.00 D does not provide full near vision rehabilitation (Alió et al., 2011). This will again help inform surgeons of the possible implantation options, and ultimately attempt to improve overall QoV.

A previous case report by Pazo et al., (2016) outlines a patient who received bilateral asymmetric multifocal IOL implantation with the near segment placed inferonasally in each eye. Postoperatively, the patient reported to have reduced visual acuity when in bright light conditions, such as when they were in a supermarket or driving during the day, and subsequently reported a poor overall QoV score. On examination, it was observed that when the pupil was constricted in photopic conditions the pupil area was occupied mostly by the near add of the IOL in the dominant eye. It was also noticed that there was an inferonasal shift in the pupil centre when the pupil constricted. A high exposure of the near add in a constricted pupil was deemed the reason for poor vision in bright light conditions, and the inferonasal pupil shift may have further enhanced the patient's symptoms. The position of the near segment was then rotated to a superotemporal placement to maximise the distance zone of the IOL in photopic conditions. Following rotation of the IOL the patient reported to have improved visual acuity and a superior overall QoV score. From this case report, it is evident that the area of exposure of the two separate sections of an asymmetric multifocal impacts the performance of the IOL. The occlusion of either the distance or near zone by the pupil can reduce visual acuity and overall QoV. To further investigate the potential factors that can cause a reduction of adequate IOL exposure, my future research will focus on the centration of the IOL and the impact of the pupil size and in particular pupil shift between mesopic and photopic conditions. To assess this, I will investigate IOL centration and how this differs in various rotational positions. This will determine if there is a significant change in IOL centration between the various placements and the centre of the pupil. Next, I will investigate the change in pupil size between mesopic and photopic conditions in combination with the pupil shift. The pupil shift is important because this can further increase or indeed decrease the area of the IOL that is exposed within the pupil (Pazo et al., 2016). Assessment of the pupil shift will be performed with the Aladdin biometer (Topcon), first to assess the repeatability of this measure and then demonstrate if this measure can be used preoperatively with each patient in combination with pupil diameter to determine the area of IOL exposure within the pupil diameter postoperatively. This information will add to existing knowledge that a combination of superotemporal placement in the dominant eye with inferonasal placement in the nondominant eye enhances QoV as seen in paper VI. In theory, if it is known that a rotational position of the IOL consistently results in a certain magnitude and direction of decentration, and a patient has a pupil shift with a particular magnitude and direction the IOL can be positioned to enhance the exposure of either the distance or near zone.

Furthermore, my future work will also include the investigation of the impact of different lifestyle groups on the item ordering of visual symptom items and misfit statistics of ophthalmic questionnaires, through the alternative approach, to allow further appropriate preoperative subcategorisation of patient groups. Additionally, further investigation of the QoV questionnaire to determine if it can be reduced by the removal of any of the current items, and assessment of the relationship between the 0-10 linear score, that is now used, and the items within the questionnaire will also be conducted.

## 8.3 Summary of the Major Findings

- The shortcomings of the current most advocated use of Rasch analysis for the analysis of ophthalmic questionnaires were outlined. It was found that a QoV questionnaire was “Rasch-valid” at 1-month however with the same cohort of patients the questionnaire was “Rasch-invalid” 12 months postoperatively. This highlights that the Rasch model cannot be used with a single and potentially non-representative cohort of patients, which is the current approach. However, instead of dispensing with Rasch analysis an alternative application was outlined. This new approach can be used as a decision support tool to provide insights at a population and individual level. The method enables investigation of the prevalence of symptoms across different cohorts of patients, and at the individual level the method enables identification of a patient that is particularly troubled by certain symptoms and further attention can therefore be provided if required.

- The use of the alternative approach of Rasch analysis outlined the impact of lifestyle on subjective outcomes of a QoV questionnaire. Rasch analysis without preoperative subcategorisation on item ordering affects the QoV measures and reduces its ability to provide adequate comparison between treatments and IOLs. Therefore, subcategorisation of preoperative groups is important to ensure like groups are compared and therefore provide a meaningful assessment and comparison of results.
- The QoV and objective outcomes of rotationally asymmetric multifocal IOLs were outlined. The newest asymmetric multifocal IOL provides excellent QoV at 3 months but significantly improves 12 months postoperatively, without a significant change in objective visual and refractive outcomes.
- The two commercially available asymmetric multifocal IOLs provide excellent QoV 12 months postoperatively, however the newest asymmetric multifocal IOL provides superior near visual acuity and spectacle independence.
- The assessment of the effect of residual astigmatism on QoV following asymmetric multifocal IOL implantation showed that there was no significant decrease in the level of QoV with increasing magnitudes of residual astigmatism, and the angle of residual corneal astigmatism does not

affect the postoperative outcomes when the IOL is placed with an inferonasal position.

- Postoperative QoV can be significantly enhanced by a combination of superotemporal placement of the near segment (+2.00 D) in the dominant eye with inferonasal placement of the near segment (+3.00 D) in the nondominant eye.

## 8.4 List of publications

### 8.4.1 Related to the thesis

<u>Publications in peer reviewed journals:</u>

1) McNeely, R.N., Pazo, E., Millar, Z., Richoz, O., Nesbit, A., Moore, T.C. and Moore, J.E. (2016) Threshold limit of postoperative astigmatism for patient satisfaction after refractive lens exchange and multifocal intraocular lens implantation. *Journal of Cataract and Refractive Surgery*, *42*(8), 1126-1134.
2) McNeely, R.N., Pazo, E., Spence, A., Richoz, O., Nesbit, M.A., Moore, T.C. and Moore, J.E. (2016) Comparison of the visual performance and quality of vision with combined symmetrical inferonasal near addition versus inferonasal and superotemporal placement of rotationally asymmetric refractive multifocal intraocular lenses. *Journal of Cataract and Refractive Surgery*, *42*(12), 1721-1729.

3) McNeely, R.N., Pazo, E., Spence, A., Richoz, O., Nesbit, M.A., Moore, T.C. and Moore, J.E. (2017) Visual outcomes and patient satisfaction 3 and 12 months after implantation of a refractive rotationally asymmetric multifocal intraocular lens. *Journal of Cataract and Refractive Surgery*, *43*(5), 633-638.
4) Moore, J.E., McNeely, R.N., Pazo, E.E. and Moore, T.C. (2017) Rotationally asymmetric multifocal intraocular lenses: preoperative considerations and postoperative outcomes. *Current Opinion in Ophthalmology*, *28*(1), 9-15.
5) McNeely, R.N., Pazo, E., Spence, A., Richoz, O., Nesbit, M.A., Moore, T.C. and Moore, J.E. Visual quality and performance comparison between 2 refractive rotationally asymmetric multifocal intraocular lenses. *Journal of Cataract and Refractive Surgery, 43(8), 1020-1026.*

Submitted papers

1) McNeely, R.N., Moutari, S., Arba-Mosquera, S., Verma, S. and Moore, J.E. An alternative application of Rasch analysis to assess data from ophthalmic patient-reported outcome instruments. *Plos One*
2) McNeely, R.N., Moutari, S., Pazo, E., Nesbit, M.A., Moore, T.C. and Moore, J.E. The use of an alternative application of the Rasch model to assess the impact of lifestyle on the responses of a quality of vision questionnaire. *Investigative Ophthalmology and Visual Science.*

### 8.4.2 Other publications

Publications in peer reviewed journals:

1) Pazo, E.E., Richoz, O., McNeely, R., Millar, Z.A., Moore, T.C. and Moore, J.E. (2016) Optimized visual outcome after asymmetrical multifocal IOL rotation. *Journal of Refractive Surgery*, *32*(7), 494-496.

Publications in non-peer reviewed journals:

1) Moore, J.E. and McNeely, R.N. The Lens: SBL-3. CRST Cover Focus January 2017.

Conference oral presentations:

1) Physiological variations in pupil size and eccentricity of visual axis (angle kappa) impact quality of vision in asymmetric multifocal intraocular lens implants. Barcelona 2015 XXXIII Congress of the ESCRS. September 2015
2) Functional and neuroadaptive effects in cataract and clear lens extraction characterised via a Quality of Vision Questionnaire. Barcelona 2015 XXXIII Congress of the ESCRS. September 2015
3) Optimal pupil size for asymmetrical multifocal intraocular lens. Copenhagen 2016 XXXIV Congress of the ESCRS. September 2016
4) Eye massage: The Impact on Clinical Signs and Quality of Vision. ICO Annual Conference Killarney May 2016

5) Comparison of visual performance and quality of vision at two postoperative assessments following bilateral implantation of a rotationally asymmetric multifocal intraocular lens. Lisbon 2017 XXXV Congress of the ESCRS. October 2017

Abstract/poster (non-oral) presentations:

1) Eye massage: The Impact on Clinical Signs and Quality of Vision. ICO Annual Conference Killarney May 2016
2) Visual outcomes and patient satisfaction three and twelve months after implantation of a new refractive rotationally asymmetric multifocal intraocular lens. Copenhagen 2016 XXXIV Congress of the ESCRS. September 2016

**8.5 Concluding remarks**

The research focused on investigating the use of Rasch analysis on ophthalmic questionnaires, and outlined the shortcomings with this current most advocated method. A novel approach for the use of Rasch analysis as a decision support tool at the population and individual level was also presented. Furthermore, the use of this novel stratified approach to subcategorise preoperative patient groups was outlined, to allow more accurate use of ophthalmic questionnaires. This research demonstrated the outcomes of asymmetric multifocal IOLs up to longer postoperative outcomes, and outlined methods of optimising patient satisfaction. This research is informative for clinicians as it outlines the correct use of ophthalmic questionnaires, which is now an important aspect of postoperative assessment, and outlined the performance of asymmetric multifocal IOLs and how to optimise postoperative QoV outcomes.

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# 9. Appendices

## 9.1 Consent form

**Lens and Cataract Surgery Consent 2016**
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### Introduction
This information contained in this consent form is about lens and cataract surgery. You should ask questions about the procedure and have them answered to your satisfaction.
Modern lens or cataract surgery is one of the most common elective surgical procedures. The aim of surgery is to safely remove the human lens of the eye and replace it with an intra-ocular lens implant. Over recent years there have been major changes in surgical technique.

### What is refractive lens exchange?
Refractive lens exchange is where small-incision lens extraction surgery is performed for correcting refractive error (long sight or short sight) or the treatment of presbyopia (the need for near vision or reading glasses). The use of a lens implant to correct the refractive error or spectacle/contact lens error (refractive surgery) is performed throughout the world. An alternative to refractive lens exchange is to wear glasses or contact lenses
A single focus lens implant provides a single focus which may be targeted as a distance focus in both eyes. Alternatively, the target may be distance in one eye and a nearer focus point in the other eye (monovision or blended vision).
A multifocal or accommodating (focusing) lens implant provides a dual or multiple focus for both distance and middle focus.
An enhanced depth of focus lens implant provides distance vision, intermediate vision, but also provides some near focus for some practical near tasks, but is not specifically manufactured to provide small print reading.
Any lens exchange or lens replacement treatment does not correct amblyopia (lazy eye) or other pre-existing eye conditions such as macular degeneration or glaucoma.

### What is cataract?
Cataract is where the lens inside the eye becomes less clear or cloudy so that light is scattered or blocked and vision is impaired. It may be like looking through frosted glass or there may be glare in bright lights or with night driving. Commonly the spectacle prescription changes as cataract changes the way light is refracted or bent. A common sign of cataract developing is gradual worsening of the vision and it is not fully correctable by glasses.

### What is cataract surgery?

Cataract surgery is where small-incision lens extraction surgery is performed in order to remove the natural human crystalline lens where cataract is present. A lens implant is used that aims to provide the desired focus after surgery. Surgery also aims to improve night driving and vision in dim light. The alternative to surgery is to use the best possible spectacle correction; this commonly improves the vision, but does not correct the vision to normal. Treatment does not correct amblyopia (lazy eye) which was present before cataract developed.

**Other conditions**

Other eye problems can reduce vision which lens or cataract surgery cannot correct. Retinal "macular degeneration", glaucoma, or other retinal problems affect the prognosis after lens or cataract surgery.

Dry eye and blepharitis (inflammation of the eyelid margins) increases in incidence with age and is present in many who seek lens or cataract surgery, and is more evident in previous long term contact lens wearers. It is a common reason to stop contact lens wear. Dry eye symptoms or blepharitis can occur after treatment and if there is pre-existing dry eye or blepharitis, ophthalmic surgery can cause this to worsen and additional management may be required after surgery.

**When should one consider surgery?**

The appropriate time to consider surgery is when there is a desire for surgical refractive correction, or when your vision is affected by cataract which correspondingly is affecting your lifestyle or activity.

In the early stages of cataract there may be minimal impact upon vision, however as the cataract progresses, the impact upon vision also starts to impact upon lifestyle. Many people who want to continue with an active lifestyle undergo early cataract surgery to ensure that their driving ability or other activities are not impacted upon.

If undergoing lens surgery is a means to reduce the requirement for spectacles or contact lenses (refractive lens exchange), there is no time limit as to when this can be performed.

Surgery is an entirely elective procedure and does not have to be performed. This applies whether the surgery is being performed for cataract or as a refractive surgery procedure (refractive lens exchange).

**Biometry**

Biometry is the measurement of the eye to calculate the necessary optical power of the lens implant. The curvature of the cornea at the front of the eye and the length of the eye are assessed. More advanced additional measurement of the thickness of the lens of the eye can further advance the accuracy of the calculation, especially using advanced software to calculate the lens implant power.

Due to there being some unpredictability in biometry assessment, there is always some scatter in refractive outcome following surgery. If the lens implant power proves to be significantly different from that intended, laser refractive surgery or ‘piggyback’ lens surgery can normally be performed to refine the refractive outcome.

In some extreme cases, the lens implant can be removed and be replaced with a different lens implant, but this involves additional risks such as retinal detachment, dislocation of the implant, pupil damage and poor positioning of the new implant. These possible complications will be discussed in depth if this mode of management has to be selected.

Cathedral Eye Clinic uses sophisticated biometry equipment and advanced software for lens implant calculation.
If you have had previous laser eye surgery (LASIK, LASEK or PRK), radial keratotomy or other corneal eye surgery the calculations for biometry are more complex and there is more unpredictability in outcome.

**4. Other Critical Measurements**

- A scan - This ultrasound scan technology is used to obtain accurate information of the eye in patients where dense cataracts prevent other scans to be used. The information obtained is then utilised in the different formulae to calculate the most accurate strength of intraocular lens implant to be used.
- Pentacam (Cornea and Retina) - This instrument generates sharp images and accurate information of the anterior segment and posterior segment of the eye in 3 dimensions.
- OCT (Cornea and Retina)- Ocular Coherence Tomography is the latest imaging technology which provides accurate colour and black and white images of the cornea, the anterior segment (cornea and natural lens), and all the retinal layers. This assists the physician to make correct critical decisions during planning of possible laser surgery, cataract and lens surgery, as well as about retinal and optic nerve conditions such as macular degeneration and glaucoma.
- Pupillometry - Pupil size is an important measurement to determine and assist your consultant in selecting the best lens option according to pupil size.
- Corneal aberrometry - Imperfections and inaccuracies in the cornea causes imperfect or inaccurate visual information to enter the visual system. This leads to an imperfect or unfocused image being formed on the retina. A corneal aberrometry measurement measures the inaccuracies and imperfections in your cornea, and this total measurement is used to determine whether you are a better candidate for a single focus/monofocal lens, or whether you can be considered for one of the more complex premium lens choices.
- Ocular dominance - Ocular dominance is a natural phenomenon which is established in the visual cortex of the brain at a young age. Your clinical team and consultant will determine ocular dominance, which will assist them to best select the correct lens combination for your dominant and non-dominant eyes.
- Stereo acuity or depth perception - This information is documented as it assists the clinical team to select the best intra ocular lens for you as an individual.
- Endothelial cell count (ECC) - A specular microscope is used to provide an accurate assessment and cell count reading of the inner layer of the cornea (endothelium).
- Ocular motility and the assessment of a possible squint. It is important to inform your clinical team if you are aware of a history of squint in the past, or whether you have a prism lens in your current spectacles. Patients with pre-operative squints, will experience the same situation after surgery. You may also present with double images following surgery. This information is critical to ensure that

your clinical team and consultant make the correct decision regarding the safety of surgery, and will also enable them to assist you in selecting the correct lens option should you be a candidate for cataract or lens exchange surgery.

**The Lens Implant**

Lens or cataract surgery can be an opportunity to correct or reduce pre-existing myopia (short sight/near sight), hyperopia (long sight/far sight/distance sight) and astigmatism (oval shaped cornea rather than spherically shaped cornea).

Correcting these shortcomings in your optical system helps to focus the image on your retina, and can therefore reduce your dependency upon spectacle- or contact lens wear.

Premium lenses are designed to provide the sharpest possible focus of an image.

These modern day premium lenses are commonly aspheric to improve the overall focus of the eye.
These lenses can be single focus, change focus, enhanced depth of focus, or multifocal.
During your pre-operative consultation and assessment, we determine which eye is the dominant and which eye is non-dominant. This information is used to select

**Monofocal Lens Implant**

There are 3 basic options or combinations to choose from if you are a candidate for a monofocal/single focus lens implant.

Monofocal lens option 1. (Distance vision).
Both eyes are set for clear distance vision focus.
Near vision spectacles or reading spectacles will be required for **all** close or near focus tasks. Any object within arm's length will not be properly focused, therefore you will rely on near vision glasses for all near tasks.

Monofocal lens option 2. (Near vision).
Both eyes are set for clear near focus.
Intermediate and distance vision will not be focused, therefore spectacles or contact lenses will be required to bring intermediate and distance objects into focus. This is particularly important for tasks such as driving.

Monofocal lens option 3. (Monovision, blended vision or micro-monovision).
The dominant eye is set for distance vision.
The non-dominant eye is set for near vision.
Patients with monovision/blended vision still have some visual compromise, as both eyes are not focused at the same point.
Many patients still have reduced dependency on spectacles but commonly need glasses to read small text.

Basic single focus lenses are readily available, but the premium aspheric, single focus lenses are the preferred choice of mono-focal lenses in Cathedral Eye Clinics' practice. These include the Lentis 313, Zeiss CTasphina 404, and Softec HD Lenstec lenses.

**Multifocal Lens Implant**

Consultants at Cathedral Eye Clinic are constantly assessing results from all patients to enable changes in practice to be implemented and compared to previous quality of vision results should new technology reach clinical practice.

As a result of this, we use an array of multifocal lenses, and select the lens to be used during your surgery, according to the clinical findings during your examination, as well as to suit your specific needs.

**<u>How does a multifocal lens work?</u>**

A multifocal acrylic lens splits the focus for incoming light such that light is focused for distance, middle distance and near distance focus.

The aim of a multifocal lens is to provide good all round vision, and to achieve less spectacle dependancy for the patient.

Some patients achieve total spectacle dependency, and although this would be the aim for every patient, total freedom from spectacles or contact lenses cannot be guaranteed.

Although we use advanced technology to obtain precise measurements, and we use advanced technology, equipment and lens implants during surgery, glasses or contact lenses may still be required for precise vision and for specific tasks such as reading or driving after surgery.

Following surgery with any multifocal lens implant, there may also be some increased awareness of glare and optical side effects(dysphotopsias) in certain light conditions, especially in bright artificial lighting conditions, dim or lower light conditions, and during driving at night.

Driving towards oncoming headlights may be particularly difficult. Some patients adapt easily to these phenomena, but due to individual differences between patients, some people adapt more slowly.

This adaptation is called visual neuroadaptation, and any individual's visual system can take up to 12 months to fully adapt to the new image and visual side effects or dysphotopsias.

Although these side effects are more commonplace with multifocal lenses, they can also occur with monofocal lens implants.

It is critically important to understand and assess the information which the clinical team and consultant will share with you during your consultation process.

You will be given enough time between your consultation process and your proposed surgery, to review the information provided, and to further explore the websites regarding this topic.

Once you have understood this information and you have reached a decision, you should sign the consent form with the selected surgical and lens implant option.

We use most types of multifocal lens design options at Cathedral Eye Clinic, and the decision to use a specific multifocal lens, or a combination of different multifocal lenses(mix and match), is decided upon once all the specific ocular measurements have been obtained, and you have had a discussion with the clinical team and consultant regarding your specific visual needs or requirements.

<u>The following multifocal lens designs and lens options will be considered:</u>

1. Refractive design.
2. Diffractive design (AMO ZCB+3.25 and +2.75Add lenses)
3. Refractive aspheric 'bifocal' design. (Lenstec SBL3 lens, Oculentis MF MPlus-15 'Comfort' lens, Oculentis MF 20 lens).
4. Trifocal design.
5. Enhanced aspheric enhanced depth of focus design. (AMO Symphony TM lens).

Even with the most advanced multifocal lenses, glasses or contact lenses may still be required after lens replacement surgery.
Some people demand very high quality distance vision in order to be able to perform certain critical tasks.
Where night driving as a profession is a significant consideration, a monofocal rather than a multifocal lens implant should be carefully and seriously considered.

People in certain professions with specific visual requirements, would not normally be advised to select a multifocal lens implant.

Commercial and private pilots may have licence restrictions according to their professional regulatory bodies and organisations.
We therefore advise all people who are in possession of a PSV, HGV or PPL licence, to check with their regulatory bodies and organisations, and to have written advice as proof from these organisations, as to regulations and eligibility to have a multifocal lens implant.
Pilots should check with the CAA / FAA as to current regulations and requirements regarding lens implants.

Some people (rare) who have had multifocal lenses implanted, have later requested lens removal and implantation of a single focus/ monofocal lens implant. This request is most commonly due to the specific patient's inability to adapt to the multifocal image or to the haloes, starburst, shadowing and glare that some patients experience following multifocal lens implantation.
It is not advisable to replace one multifocal lens with another type of multifocal lens following an explant.
Following multifocal lens removal and subsequent monofocal lens implant, reading glasses are normally required for computer screen vision or near vision tasks, especially reading.

The decision to remove a multifocal lens (due to the fact that a specific patient struggles to adapt to the multifocal image, or to the dysphotopsias), is not a decision which is taken lightly. All options to ensure that a patient has taken sufficient time to allow neuroadaptation to take place, will have been tried and will have been exhausted.
The significant risks of damage to the cornea, iris, pupil, capsular bag, and the increased risk of retinal detachment following intraocular lens removal, makes the decision a serious one, and intraocular lens removal will only be considered as a last resort.

Statistics related to various different multifocal lens implants and dysphotopic side effects are as follows:
Refractive multifocal(30%), 15 of 45 patients vs. monofocal(15%), 7 of 45 patients.
Diffractive multifocal(26%), 21 of 79 patients vs monofocal (12%), 9 of 70 patients.
In total, 40%(65 of 162 patients) in the multifocal group and a total of 18%(29 of 157 patients) in the monofocal group experienced dysphotopsias.

In another study, 3 month postoperative results in patients with a refractive segmented multifocal/bifocal lens such as the Oculentis MPlus lens and the Lenstec SBL3 lens, statistics are as follows:
32.7% of patients had no glare at night.
43.2% of patients had a little difficulty with glare at night.
18.5% of patients had moderate difficulty at night.
5.7% of patients had severe difficulty with glare at night.

In the same study, 93.8% of patients at the 3 month post-operative period were satisfied to very satisfied with their visual outcome following the lens procedure.

**Colour vision**

As the years pass our colour perception changes and the natural lens in the eye scatters and absorbs blue light selectively. After surgery the lens implant is very clear, and therefore a change in colour perception is common. This can be dramatic, especially in the early post-operative period.

Colour discrimination is subjective and many people experience a change in colour awareness following surgery with an intraocular lens implant. Some people experience a dramatic colour change perception after lens surgery. In these patients, black colours can appear deep navy, and brown colours can appear purple or magenta.

All lens implants have ultra violet (UV) blocking properties. We still recommend that patients use sunglasses when outdoors to block excess UV light reaching the retina of the eye.

Where colour discrimination is very important, please inform your surgeon, as a special lens can be implanted to provide enhanced depth of focus with good UV blocking.

**The Procedure Options**

Cathedral Eye Clinic surgeons will specifically advise you about your particular clinical findings, and will advise and assist you in selecting the best option for your personal requirements.

| | | |
|---|---|---|
| Surgery Procedure | Phakoemulsification | Standard or minimal access phakoemulsification |
| Lens implant | Basic single focus lens | Premium lens which may be aspheric single focus, enhanced depth of focus, or accommodating |
| Astigmatism | Not corrected | Corrected arcuate astigmatic treatment. or for large astigmatism toric IOL +/-bioptics, where excimer laser eye surgery is performed as a second procedure) |

Since this procedure is designed to be a permanent and non-reversable solution, most people in Cathedral Eye Clinical practice elect for premium options in order to maximise the likelihood of the best possible visual outcome.

It is of utmost importance to make an informed decision as to which lens option best suits your personal needs.

We always aim to obtain the most accurate biometry (calculation of lens implant power). Astigmatism must be reduced or corrected to achieve best vision without glasses.

**Local anaesthesia**

Modern techniques avoid needle injection, are normally painless and provide effective anaesthesia. There is no need to avoid eating prior to surgery. You will have the opportunity to meet with the anaesthetist to discuss the local eye block procedure prior to surgery. Should you have the need to discuss the procedure prior to your day of surgery, this could be arranged in advance.

It is preferable to continue taking all the chronic medication that you usually take, as you normally do, prior to surgery.

**Phakoemulsification procedure**
On the day of surgery you will be checked in by the ophthalmic nurse who will ensure that your pupil is well dilated prior to proceeding to surgery.
Surgery is normally performed by ultrasound phakoemulsification ("phako") technique. This procedure is performed through a very small, self sealing corneal incision (2.50 mm or 2.75 mm wide). There is usually no requirement for a suture in the wound. On rare occasions, the surgeon may decide to place one or more self absorbing sutures in the incision, but this is done only to prevent a specific wound from leaking following surgery.

Surgery usually takes approximately 15 minutes. A small self-sealing incision is made in the cornea of the eye, using a purpose-designed keratome instrument. One smaller side incision is also created. This technique has been consistently improved over the last 20 to 30 years so that it is most likely that one can expect predictable and high quality outcomes.

The incisions are created by your surgeon with the aim to either reduce pre-existing astigmatism or to ensure that the effect is neutral and does not increase pre-existing astigmatism.

Your consultant surgeon firstly opens the capsule using a consistent and accurate technique. An ultrasound Phaco probe is then used to emulsify (liquefy) and remove the lens. Following lens removal,an injectable, folded lens implant is carefully injected through the small incision into the eye. The lens then unfolds within the capsular bag of the eye to remain within the normal anatomical position of the patient's own lens which has just been removed, and in the process, restores vision.

**After surgery**
At the end of the procedure, protective antibiotic and anti-inflammatory (steroid) solution is applied and an eye shield is placed over the eye.
Each patient will then be accompanied to the recovery room to receive a cup of tea, coffee or cold beverage.
The postoperative eye medication will be thoroughly explained to you prior to leaving to return home. You will normally be supplied with 2 or 3 bottles of eye-drops, which are to be used regularly to protect the eye for a period of 4 to 5 weeks.
Follow- up examinations are scheduled for 2-5 days and then again 4 weeks later. Depending upon the type of surgery, ongoing follow-up may be required and may continue for up to a year.

The procedure itself and the medications and preservatives prescribed after surgery can exacerbate pre-existing dry eye symptoms, or cause dry eye type symptoms postoperatively.
Itching after surgery is most commonly secondary to developing allergic type symptoms to the preservatives used in eye-drops, and a change to preservative-free drops may occasionally be required.

**Surgery to both eyes**
Consultant surgeons at Cathedral Eye Clinic do not advise that both eyes are operated upon at one sitting. There is usually a one-week delay between the first and second eye procedures.
This allows both the patient and the consultant surgeon to evaluate the outcome of the first procedure, before proceeding to second eye surgery.

Occasionally, and only under special conditions and circumstances, the second eye will be treated 2-3 days after the first procedure. This will only be done once the surgeon has carefully examined the outcome and condition of the eye which has already been operated, and once the surgeon is satisfied that it is safe to proceed with second eye surgery.

**Outcome after surgery**
Your consultant surgeon will always endeavour to actively manage astigmatism at the time of surgery to attempt to reduce it to improve unaided vision. The aim is to minimise astigmatism to an acceptable level, or to eliminate astigmatism altogether. This will result in better depth of focus, and better clarity and quality of vision.
It is very common to have residual astigmatism, which if significant, may require further laser eye surgery to reduce astigmatism to an acceptable level.
This type of management is called bioptics, and can be achieved by using corneal laser refractive surgery, or by placing an additional piggyback lens in front of the existing implanted lens.

Following lens implant surgery, vision is usually very clear if compared to pre-operative clarity and quality of vision. Patients often notice a change in colour vision, with colours appearing much more vivid again. This is more apparent if the vision was reduced by cataract.
Bright daylight can occasionally be uncomfortable at first, and patients may want to wear sunglasses initially until they have adapted to the ‘new vision’.
Clear vision normally returns within hours or days, though it takes a number of weeks to gain the optimal vision post-surgery.

The outcomes following lens based intraocular surgery, are always slightly unpredictable. It is important for patients to understand that though the aim after surgery is for the best possible visual outcome, like all surgery, there will be a scatter in results and the refractive outcome remains slightly unpredictable. It is therefore reasonable to expect that spectacles may be required for some tasks after surgery. If the lens implant power proves to have a result which is significantly different from the intended aim or outcome, and there is significant myopia, hyperopia or astigmatism, further correction using corneal refractive laser or piggyback lens implant can be considered.

It is of utmost importance to use your prescribed eye drops after surgery and to attend for follow-up assessment as advised. After surgery, you may resume driving when you have been advised that you fulfil the legal visual standard requirements for driving. Specific advice regarding this is given at your follow-up consultation.

It is advisable to have periodic review by your local optometrist to monitor the health of the eyes in the long term.

**Myopia (short sight, near sight)**
In myopia, the eye has grown larger than normal and light is focused in front of the retina. There is an increased risk of retinal detachment in myopic patients when compared to their non-myopic counterparts.
I myopic patients under the age of 50 years, and with an axial eyeball length greater than 26.5mm, the risk to develop retinal detachment following lens replacement surgery is 10 times greater than the risk for non-myopic patients. The retinal detachment risk in the normal population averages 0.7% following lens replacement surgery. This means that the risk in this high myopia group is 7% (7 patients out of a hundred patients)

Following lens replacement surgery, myopic patients experience a greater sense of loss of near vision ability. The use of increased depth of focus lenses such as the AMO ComfortTM is then very well appreciated when there is high myopia pre-op. For some cases of high myopia, a **specialist lens** may need to be ordered which may result in a longer waiting time prior to surgery taking place.

**Complications & risks of surgery**
Although highly effective, lens/cataract surgery like any significant operation is associated with complications. Because lens/cataract surgery carries a small risk of loss of vision and serious infection within the eye, then most commonly one eye is operated upon at a time. About 1% is expected to have some issue, which settles with time (such as inflammation). About 1 in 1000 is expected to have a more serious issue, which could permanently reduce visual quality. Such complications, which may cause this to occur, would be infection or haemorrhage (bleeding into the eye). More serious loss of vision such as a serious haemorrhage is expected to occur in about 1 in 4000.

Being pregnant or lactating is a contraindication to having treatment since the effects of treatment are unknown in pregnancy and the effects of pregnancy upon the result of the treatment are also unknown. If you become pregnant after treatment there is no evidence that treatment affects pregnancy or any of the sight and scanning tests performed.

**Possible complications — for femtosecond laser and manual surgery**

- Incomplete capsulotomy with radial tear or breakage/tear of the posterior lens capsule. As the lens capsule is the capsule which holds the new Intra-Ocular Lens (IOL) in position, a defect in this capsule during surgery may warrant the surgeon to perform a partial vitrectomy (removal of the vitreous gel) and placement of the lens might still be possible ‘in the bag/capsule’. Should this not be possible, the lens will be placed in front of the bag (in the sulcus), which still results in good quality of vision. Should either of these mentioned options not be possible, a further procedure will be scheduled at the appropriate time, usually within a week, to rectify the situation. Retinal detachment risk is increased following a capsule break or capsule tear followed by a vitrectomy.
- Statistics for capsule tear is 0.24%-2% of cases in the UK
- Phakoemulsification equipment malfunction.
- Endophthalmitis (infection & inflammation developing within the eye after surgery). (0.025%-0.049%)
- This complication is rare, but can lead to severe visual loss or loss of the eye in rare instances.
- Expulsive Haemorrhage (bleeding behind the retina). This complication is extremely rare, but leads to severe visual loss in most instances, and in some cases there is total loss of the eye. Statistics: (0.04% or 1 in 2,400 cases[2])
- Bullous keratopathy / corneal decompensation / corneal oedema /corneal clouding. This complication is rare with modern cataract surgery and phaco-emulsification techniques and equipment. It occurs more commonly in patients with a defective inner layer of cells on the cornea, called an endothelial dystrophy. Should you have an endothelial dystrophy, your clinical team and surgeon will discuss this with you prior to you making a decision regarding your potential surgery. Statistics: 0.4%-5.0% in the UK.

- Dislocation of the lens implant (implant not centred properly). Dislocation of the lens implant is due to a defect in the capsular bag, or due to a defect in the zonules or ligaments which keep the lens in position.
- Cystoid macular oedema (fluid in the area of critical vision in the retina). This complication is usually transient, and is managed on an outpatient basis with eye drops and tablets. Should it persist, there may be a need for intravitreal

injections. This complication can cause a decrease in the quality of the image and is a more common complication in patients with certain retinal conditions such as Diabetes and Macular Degeneration statistics: 1-2% of cases[1]

- Retinal detachment
- Statistics 0%- 3.6% and averages 0.7%[7]
- Double images, shadowing, glare, starburst, haloes and other optical side effects (dysphotopsias)[9].
- Leaking wound.
- Post-surgery chronic inflammation, pain and discomfort, photophobia (glare).
- Droopy eyelid (ptosis) which is rare with modern surgery.
- Refractive error after surgery which may be myopia, long-sight and or astigmatism.
- Glaucoma.
- Defective lens implant, lens implant unusable at the time of surgery or not possible to safely implant a multifocal lens implant or use any lens implant at the time of surgery.
- Difficulty with any future retinal detachment surgery with certain lens implants.
- Visual acuity is affected or altered if a patient develops conditions which may affect the macula (area of critical vision), for example: macular degeneration, arterial or vein occlusion in the retina, diabetes which affects the macula. The vision is more severely affected or altered if a multifocal lens has been implanted in these cases.
- Floaters due to the vitreous gel being stirred up by the manipulations of surgery.

**YAG laser treatment / cloudy capsule** (5-10% of patients within 1-2 years post op)[10]
After several months or years after surgery the vision may become blurry again. This is commonly due to clouding of the thin, transparent membrane behind the IOL, which used to contain the natural lens before it was surgically removed. This "lens capsule" sometimes gradually becomes cloudy. It is treated using a "YAG laser". This involves only an outpatient visit. It is very effective, painless and the infrared laser beam cannot be seen. However, the laser can very occasionally cause retinal detachment or swelling of the macular part of the retina due to small shockwaves.

The risk is minimised by deferring YAG treatment after lens extraction surgery by at least 3 months. After YAG laser treatment there may be floaters, which commonly are transient over a few days, but they can persist for a long period of time. There are additional fees for the YAG laser capsulotomy procedure, which is not included in the surgery fee, or the YAG procedure can be performed within the NHS.

The risk is minimised by deferring YAG treatment after lens extraction surgery. After YAG laser treatment there may be floaters, which commonly transient over a few days, but they can persist for a long period of time. There are additional fees for the YAG laser capsulotomy procedure, which is not included in the surgery fee, or the YAG procedure can be performed within the NHS.

**Proprietary interest statement**
Professor Moore is Consultant Ophthalmic Surgeon at Cathedral Eye Clinic; he is also Medical Director. He helped create the online cataract and refractive course which is now co-badged by the Royal College of Ophthalmology. He was anterior segment lead at the Royal Victoria Hospital. He has been a Consultant advisor to Oculentis manufacturer of lens implants and consults for Lenstec USA. Professor Moore is on the UK Specialist Medical Register.

**Contact numbers**
Cathedral Eye Clinic
Belfast

02890 322020

**Confidentiality**

If you are a UK resident your General Practitioner (or internationally your medical advisor) will normally be informed regarding your treatment unless you decline informing your GP / medical advisor.

**Consent for Surgery**

Carefully read each paragraph/statement and having read and understood each statement please initial each on the dotted lines that follow each section. In signing this form, you are stating that you have read and understand this consent form. Although it contains medical terms that you may not completely understand on first reading, you have had the opportunity to ask questions and had them answered to your satisfaction such that you understand the information on this form. I declare that I have read and understood the following information:

1. Refractive lens exchange or cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. Lens implantation is where an artificial lens is placed inside the eye in the place of the natural human lens.

| **Patient Initial of Understanding** | |
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Complications of surgery to remove the human lens within the eye can occur and as a result of surgery it is possible that my vision could be made worse. In some cases, complications may occur weeks, months or even years later. Complications may include haemorrhage (bleeding), loss of corneal clarity, retained remnants of the lens within the eye, infection, detachment of the retina, uncomfortable or painful eye, droopy eyelid, glaucoma (raised pressure in the eye). These and other complications may occur whether or not a lens is implanted and may result in poor vision, very rarely total loss of vision, or even loss of the eye in very rare situations. There is a potential 1 in 13,000 (or less) risk of sympathetic ophthalmia where there is a risk to the other eye due to an immune reaction developing. This is whether or not the femtosecond laser is used during surgery. Complications may also include uveitis (inflammation within the eye), iris atrophy, fixed dilated pupil or inability to dilate the pupil, increased night glare and/or halo, double or ghost images, dislocation of the lens and retinal detachment. There may be a chronic ache within the eye, though this is very rare and there may be dysphotopsia (reflections from the lens implant within the eye). The procedure itself, the medications and preservatives after surgery can worsen or cause alteration in Meibomian gland function at the eyelid margin and produce or exacerbate dry eye symptoms such as burning, dryness, irritation, redness.

| **Patient Initial of Understanding** | |
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Even with the most advanced technology for assessment the intraocular lens power measurements may vary, resulting in the need for corrective spectacle lenses or surgical replacement of the intraocular lens. Refinement of refractive outcome may be required such that excimer laser refractive surgery may be required to reduce any residual spectacle prescription.

| **Patient Initial of Understanding** | |
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When an intraocular lens is implanted, it is intended that the small acrylic or silicone lens will be left in my eye permanently.

| **Patient Initial of Understanding** | |
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At the time of surgery, very rarely, Professor Moore may decide not to implant an intraocular lens even though I may have given prior permission to do so. This is where it is deemed unsafe for a lens to be implanted at the time of the lens extraction surgery, or where the situation means that implanting a lens at a later date would involve a better outcome or lower risk. I understand that at the time of surgery it may be best not to have the Intended lens (such as a multifocal lens) implanted and I may receive an alternative monofocal lens implant. This is rare, but a multifocal lens must be perfectly positioned and if the lens is not stable then an alternative monofocal lens may be best

| **Patient Initial of Understanding** | |
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The results of surgery in my case cannot be guaranteed. Additional treatment and/or surgery may be necessary. I may need future YAG laser surgery to correct clouding of vision due to the capsule of the lens clouding after phako surgery. At some future time, rarely, the lens Implanted my eye may have to be repositioned or removed surgically (rare).

| **Patient Initial of Understanding** | |
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The basic procedures of the lens/cataract surgery to the eye if applicable, and ultrasound phakoemulsification surgery, and the advantages and disadvantages, risks and possible complications and alternative treatments have been explained to me. Although it is not possible to inform me of every possible complication that may occur, all my questions have been answered to my satisfaction. In signing this informed consent for refractive lens exchange or cataract surgery, and implantation of an intraocular lens, I am stating I Have read this informed consent and I fully understand it and the possible risks, complications and benefits that can result from the surgery. My decision to undergo surgery has been my own and has been made without duress of any kind. The nature of this surgery has been fully explained and understood by me.

| **Patient Initial of Understanding** | |
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Treatment will be to one eye only. The surgery is normally painless and there should be only minor pain or discomfort in the eye after the anaesthetic has worn off.. There is normally a rapid return of vision with much vision recovered the day after surgery. It does. however take a number of weeks to fully stabilise.

There may be "floaters" seen with the operated eye since surgery causes the vitreous jelly of the eye to be stirred up. There is a risk of retinal detachment, which is why if there are any symptoms of flashing lights, a shower of floaters, or a dark shadow that blocks vision, it is advisable to return for retinal examination. I understand I should attend for follow-up assessment and use the post-operative medications prescribed and recommended.

| **Patient Initial of Understanding** | |
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If myopia or hyperopia is corrected, after surgery there is a perceived change in the image size due to the correction of the refractive error. If spectacles are worn, then after treatment to the first eye there will be an imbalance between the eyes, unless refractive correction is performed to the second eye. It may be very difficult to tolerate the imbalance between the eyes using a spectacle correction and surgery to the second eye may be required to balance. Correction of hyperopia (hypermetropia, long-sight) means there is loss of magnification which occurs with glasses so the vision is less magnified but with wider visual field after surgery.

| **Patient Initial of Understanding** | |
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I understand that I may have some residual spectacle prescription including astigmatism after surgery, so my vision without glasses may not be as good as I wish for. I understand that I may need to wear spectacles after surgery. This is due to limitations an unpredictability with current surgical and lens technology. It is commonly possible to have excimer laser treatment to reduce any myopia, hyperopia and / or astigmatism. This entails a further surgical procedure with attendant risks and further cost that may not reimbursed by any medical insurance.

| **Patient Initial of Understanding** | |
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If a premium aspheric lens implant is used, I understand there will be an additional charge which is not normally reimbursed by medical insurance. This is also the case for additional laser eye surgery for correcting high astigmatism.

| **Patient Initial of Understanding** | |
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I understand that if I have a multifocal lens implant in one eye I will likely need another multifocal lens implant in the other eye to achieve balance and best results. Such a lens implant is not available as an NHS procedure at the present time.

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| **Patient Initial of Understanding** | |

I understand that my identity will be kept confidential in any reports or journal articles. I give permission for medical data concerning my operation and any subsequent treatment to be submitted for audit and publication. I also give permission for video recording of my procedure and broadcast to a secure website, for purposes of audit, education, research or training of other health care professionals.

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| **Patient Initial of Understanding** | |

I agree that my GP, Medical Officer and Optometrist be informed of my treatment.

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|---|---|
| **Patient Initial of Understanding** | |

I have been given a copy of this consent form to keep. I consent to the lens/cataract extraction procedure as well as for the anaesthesia and also consent to such further alternative measures as may be found to be necessary during the course of the treatment.

| | |
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| **Patient Initial of Understanding** | |

In addition to this:

| **Statements of Understanding** | **Patient Initial of Understanding** |
|---|---|
| I acknowledge that I have declared all medical and/or mental conditions I suffer from currently, or have suffered from in the past. | |
| I acknowledge that I have declared al medications (prescription or non-prescription), which I currently use. | |
| I have read all the information regarding my proposed surgery handed to me at Cathedral Eye Clinic. | |
| I am fully aware that I am under no pressure or obligation to undergo surgery, and are satisfied that the non-surgical options have been explained and offered to me as a management option. | |
| I have had a comprehensive and detailed consent process with the surgery/clinical team at Cathedral Eye Clinic, and I am satisfied that I fully understand the positive potential negative outcomes of the proposed surgical procedure. | |
| I have been provided with the internet web address of the Royal College of Ophthalmology to further read and investigate the risks and benefits of the proposed surgical procedure. https://www.rcophth.ac.uk | |
| I fully understand and acknowledge the statistics enclosed in the consent form which have been explained in understandable terminology to me by a member of the clinical/surgical team. | |

| | |
|---|---|
| I understand and comprehend that there is no guarantee of outcome as discussed during the consent process and in the supported information sheet and consent documents. | |
| I fully understand the best possible outcome/worst possible outcome and my likely outcome should I proceed with the proposed surgery. | |
| I fully comprehend and understand that any surgical/post surgical side effect or complication, be it a minor side effect or major complication, could have a serious and severe impact on my ability to perform certain tasks, and on my quality of vision and quality of life in general. | |
| I fully understand that the proposed surgery as explained in this document, does not prevent the development of naturally occurring eye problems, such as glaucoma, macular or retinal degeneration, or retinal detachment. | |
| I have been given ample time between my consultation and discussion of the procedure, until the day of surgery, to consider all the information, risks and benefits of the proposed procedure, and I am consenting to undergo this procedure of my own free will. | |

**EYE** Both eyes Right eye only Left eye only

Right eye first Left eye first

TECHNIQUE Lens implant

**PATIENT** **Signature** ______________________________ **Date** ___________

Print Name ______________________________

Surgeon Declaration: I have seen the patient prior to the date of surgery (please see signed procedure discussion sheet). The patient has read and understood the consent form, has no further questions and is happy to proceed with treatment.

**SURGEON** **Signature** ______________________________ **Date** ___________

Print Name ______________________________

**WITNESS** **Signature** ______________________________ **Date** ___________

Print Name ______________________________

| **Notes prior to 2nd eye.** |
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The patient has had a successful outcome to first eye with no post-operative concerns during follow up examination.

**Additional Notes:**

Surgeon Signature: ___________________________ Date: _______________

Print Name:____________________________

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[7] Pseudophakic retinal detachment after phacoemulsification cataract surgery: Ten-year retrospective review. Russell M, Gaskin B, Russell D, Polkinghorne PJ.
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